IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

UNDER SEAL	)	
	)	
Plaintiffs,	)	
	)	**FILED IN CAMERA AND UNDER SEAL**
	)	
v.	)	
	)	DO NOT PUT ON PACER
	)	DO NOT PUT IN PRESS BOX
UNDER SEAL	)	
	)	Jury Trial Requested
	)	
Defendant.	)	
	)	

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
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UNITES STATES OF AMERICA; the States of CALIFORNIA, COLORADO, CONNECTICUT, THE DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE TEXAS, VERMONT, VIRGINIA, WASHINGTON, ex rel. BROOKS WALLACE, ROBERT FARLEY and MANUEL FUENTES	)	Civil Action No. _____
Plaintiffs,	)	**FILED IN CAMERA AND UNDER SEAL**
v.	)	DO NOT PUT ON PACER DO NOT PUT IN PRESS BOX
EXACTECH, Inc.,	)	Jury Trial Requested
Defendant.	)	

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***QUI TAM* COMPLAINT**

Relators Brooks Wallace, Robert Farley and Manuel Fuentes, on behalf of themselves, the United States of America, and the named party States, allege and claim against Exactech, Inc., as follows:

STATEMENT OF THE CASE

1. This *qui tam* complaint alleges that Defendant Exactech, Inc. ("Defendant" or "Exactech") violated the False Claims Act (31 U.S.C. 3729 *et. seq.*) by conspiring to submit and causing the submission of false claims for payment to government health care programs including Medicare, Medicaid and Tricare programs by selling a defective medical device for use in the care of government insured patients when this device was known by Exactech to be defective and thus not reasonable and necessary for treatment, in violation of 42 U.S.C. § 1395(a)(1)(A). This complaint further alleges Exactech offered and provided illegal remuneration in order to prevent the disclosure of device failures and to induce orthopedic surgeons to continue to use Exactech products after learning the device was defective, in violation of 42 U.S.C. § 1320a-7b and in furtherance of a conspiracy to submit false claims and to conceal and avoid repayment of obligations to repay money to the Government, in violation of 31 U.S.C. § 3729(c). Exactech's scheme to continue to sell defective devices and cover-up the discovery of its defects callously caused severe patient harm to United States veterans, the elderly, and the poor, all to profit from taxpayers and avoid business losses from what should have been a large-scale recall.

2. Relators Wallace and Farley were Exactech sales representatives and later Exactech distributors and witnessed the fraud and its harmful effect on patients first-hand. Relator Fuentes is a medical doctor and was a senior member of Exactech's marketing team for the defective

device and attended closed-door meetings where Exactech's executive leadership orchestrated the fraud and cover-up.

3. From at least April 2008 until at least December 2016, Exactech sold and encouraged surgical physicians to implant the company's defective device – the Optetrak Total Knee Replacement System (Optetrak TKR) – in patients despite clear and established knowledge that an integral component of the Optetrak TKR, the "Finned Tibia Tray," had multiple design flaws resulting in a premature failure rate far beyond any acceptable failure rate of comparable total knee replacement devices. Despite Exactech's reports to the contrary, the true failure rate of the Finned Tibia Tray is known by Relators (and to Defendant) to be approximately 30-35% in the first three years – whereas the industry standard for knee replacement devices is 5% or fewer failures over a ten-year period. Essentially, Exactech continued to sell a device it knew would cause 3 out of 10 patients to suffer with continued pain and immobility until requiring painful and distressing revision surgeries — in many cases before or not long after they even recovered from the initial surgery.

4. Exactech has been able to continue selling such a woefully defective and dangerous device by perpetrating a well-orchestrated cover-up of the true nature of the failure rates and dangers associated with the Optetrak TKR.

5. This cover-up scheme – devised at the highest levels of Exatech's corporate leadership -– includes systematically concealing the existence of thousands of device failures to all interested stakeholders including hundreds of orthopedic surgeons implanting such devices, Exactech's own distributors, sales personnel, and federal government agencies including the Food and Drug Administration (FDA), Centers for Medicare and Medicaid (CMS) and the Department of Justice (DOJ).

6. Beginning, at the latest, in 2007, Exactech began receiving a deluge of reports from its distributors and surgeons using the Optetrak Total Knee Replacement that the device was failing at astounding rates due to an apparent design flaw in the "Finned Tibia Tray"—likely the most critical component of the device. To address these reports, Exactech conducted an internal investigation in late 2007 and early 2008, which included a confidential audit of patients in the practice of Dr. Ivan Gradisar. Dr. Gradisar was part of the original Optetrak TKR design team, the first surgeon to ever use the Optetrak TKR, and a "friend of the company." This confidential audit and descriptive report was delivered, by standard mail instead of email to minimize its electronic trace, to Exactech on or around April 1, 2008. This audit is attached as Exhibit A. The audit confirmed that the Optetrak TKR had material design flaws and verified the reports of device failure from surgeons using the Optetrak TKR from across the U.S. and around the world. The collateral internal investigation also uncovered several design and engineering process failures that Exactech engineers believed were the causes of the Optetrak TKR failures. Therefore, since at least April 1, 2008, Exactech has definitively known there was a major defect with the Exactech Finned Tibia Tray.

7. Possessing affirmative knowledge of both patient data demonstrating significant device failure and the probable design and process flaws causing such failure, Exactech held a series of meetings of only its top executives and engineers to determine the company's course of action. As a senior member of the Exactech knee replacement design and support team, Relator Manuel Fuentes attended these closed-door meetings and is knowledgeable of the topics discussed and conclusions reached.

8. During these meetings, Relator Fuentes directly observed corporate leadership of Exactech as they listened to reports of the internal audit, the mounting reports of device failure

and patient harm, examined the problematic issues with the Optetrak TKR, and concluded the Optetrak Finned Tibia Tray had several material design flaws and posed a danger to patients. Thus, it was initially determined that a recall was warranted and all sales of the Optetrak Finned Tibia Tray must be halted. After considering the financial ramifications of such measures, however, Exactech leadership decided that a recall—or even a disclosure of the mounting device failures—would be too financially detrimental to Exactech. Rather than institute a recall, Exactech decided to bury any evidence of the known device failures and continue to sell the Optetrak TKR. At these closed-door meetings where Relator Fuentes was present, the foundation of the massive cover-up scheme was formed, and Exactech developed the playbook of false narratives it would use to continue to manufacture and sell Finned Tibia Tray Optetrak TKRs while secretly developing a replacement product.

9. The first step in Exactech's cover-up "playbook" was to attempt to isolate those who discovered the issue and fool them into believing that they were the only ones experiencing a problem. When the corporate leadership received a complaint from a distributor, surgeon, or staff that Optetrak knee replacements were failing, Exactech lied and claimed that each successive complaint was the first news of such failures, the individual surgeon was the only surgeon from whom Exactech was receiving reports of device failure but that Exactech would investigate the complaint. Then, upon a purely cosmetic "investigation" Exactech would falsely blame each individual surgeon – stating the problem was with that individual surgeon's technique, not the device. Of course, these statements were patently false because Exactech was well aware of the material product defects and was simultaneously receiving reports of failures from surgeons across the United States.

10. The initial smoke-screen of blatant lies only stemmed the tide for so long, however, and eventually surgeons and Exactech distributors began to demand more information about the ever-mounting Optetrak failures. When faced with infuriated surgeons whose patients were returning with knee replacement implant failure, Exactech turned to the second step of its cover-up "playbook" – and silenced those surgeons with illegal remuneration in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b. This illegal remuneration most commonly took the form of "consulting agreements" offered to the infuriated surgeons. These "consulting agreements" paid the surgeons between $300-450 per hour for often simply conversing with Exactech representatives. These "consulting agreements" bought Exactech two things: (1) the surgeon's silence regarding the Optetrak TKR device failures and (2) the surgeon's future business and use of Exactech products. Therefore, these "consulting agreements" were in effect hush money for continued and future business. Many of these surgeons became unwitting pawns in Exactech's game – believing that they were the only ones experiencing problems with the Optetrak TKR device and that the consulting agreements demonstrated a willingness on Exactech's part to listen to and take seriously the expertise of the surgeon. As a result, the surgeons continued to work with Exactech with the hope that the problem would be resolved.

11. A final and encompassing step of the cover-up "playbook," was to sequester and minimize any communication or reporting about the "Finned Tibia Tray" or Optetrak TKR failures. Exactech ordered all corporate employees to cease discussing the Finned Tibia Tray or related failures by email and sought to limit communication by distributors and sales representatives in different parts of the country. Exactech further sequestered the information regarding Finned Tibia Tray failures to only a few top individuals and forbade any written communication regarding Finned Tibia Tray failures to avoid the potential detection of the

known device failure. Finally, Exactech concealed the existence of the Optetrak TKR device failures from the Food and Drug Administration (FDA) – despite affirmative, material, obligations to report such device failures under the Adverse Event Reporting guidelines. *See* 21 U.S.C. 360i; 21 C.F.R. §803.5.

12. In the few instances Exactech reported adverse events related to the Finned Tibia Tray, Exactech grossly misrepresented the nature and cause of the adverse event as if it were an isolated incident, even though corporate executives knew it was but one example of a widespread problem. Further, each adverse event reported to the FDA regarding the Finned Tibia Tray made specific false representations about the event and the efficacy of the Finned Tibia Tray. The non-disclosure of material information regarding widespread failures of the Finned Tibia Tray rendered those specific representations to the FDA false and/or misleading half-truths. Therefore, subsequent claims for payment that Exactech caused to be submitted to the government for TKR surgeries using the Finned Tibia Tray are violations of the False Claims Act. *See Universal Health Services, Inc. v. U.S.*, 136 S.Ct. 1989, 2001 (U.S., 2016).

13. Throughout this time, Exactech worked to develop and release a replacement device for the defective Optetrak Finned Tibia Tray. The Optetrak "Fit" Tibia Tray was released in October 2011, yet Exactech never alerted the FDA that the "Fit" Tibia Tray was a correction of the defective "Finned" Tibia Tray in violation of 21 U.S.C. §360i(g) and 21 C.F.R. §806.10. Furthermore, despite having a replacement device available on the market, Exactech executives decided to continue to sell the defective Finned Tibia Tray to unsuspecting distributors such as Relators Brooks Wallace and Robert Farley to clear out its remaining inventory of the defective device.

14. Further, as a publicly traded company, Exactech's frequent false representations about the efficacy of its primary product, the Optetrak TKR, executed a fraud on investors.

15. As a result of Exactech's systematic fraud, thousands of patients suffered from knee replacement device failure and were forced to undergo a far more intensive and painful Total Knee Replacement "Revision" surgery and the accompanying in-patient and out-patient care and rehabilitation –at the expense of government healthcare programs.

JURISDICTION AND VENUE

16. This action arises under the False Claims Act, 31 U.S.C. §§ 3729-33 (the "False Claims Act"). Accordingly, this Court has jurisdiction pursuant to 28 U.S.C. § 1331. Jurisdiction is also authorized under 31 U.S.C. § 3732(a).

17. Venue lies in this judicial district pursuant to 31 U.S.C. § 3732(a) because the Defendant qualifies to do business in the State of Alabama, transacts substantial business in the State of Alabama, transacts substantial business in this judicial district, and can be found here. Furthermore, Defendant committed within this judicial district acts proscribed by 31 U.S.C. § 3729, to-wit: Defendant caused to be submitted to the United States false claims for payment for a medical device Defendant knew to be defective due to its failure rate far exceeding any industry standards yet falsely represented the device was without malfunction to the FDA in violation of 21 U.S.C. § 360i and 21 C.F.R. §803.50; Defendant falsely represented to CMS that the device was safe, effective and reasonable and necessary for treatment in violation of 42 U.S.C. § 1395y(a)(1)(A) and Defendant offered and provided illegal remuneration to surgeons in order to induce the continued and future use of Exactech devices, in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b.

PARTIES

18. Relator Manuel Fuentes, MD is an orthopedic trained physician with over twenty years of experience in the orthopedic device industry. Born and medically trained in Guatemala, Dr. Fuentes entered the orthopedic device field immediately after graduating first in his Orthopedic and Trauma Residency Program and helped introduce modern Orthopedic devices, including total knee replacement systems, to Guatemala and throughout Central America. During his career, Dr. Fuentes has worked for many major orthopedic device companies, including large companies like J&J (DePuy) and Zimmer and relatively smaller orthopedic device companies like Exactech. He has worked in both design and marketing in the orthopedic industry and has held various titles, including Senior Sales Manager, Senior Product Manager, Director of Business Development and Regional Sales, and Marketing Manager. Dr. Fuentes was hired by Exactech as a Product Manager in 2006, and some of his primary responsibilities were to develop and conduct training for Exactech sales force and for orthopedic surgeons on Exactech products. In 2008, Dr. Fuentes was promoted to Senior Product Manager in Exactech's Knee Products division, where he worked until leaving Exactech in 2011. In this role, Dr. Fuentes launched several orthopedic product development projects and routinely trained and interfaced between surgeons and sales representatives in the field and Exactech corporate engineers. Throughout this period, Dr. Fuentes reported directly to Charley Rye, Director of Knee Marketing. Through this experience and his unique familiarity with both Exactech corporate policy and issues in the operating room, Relator Fuentes has detailed knowledge about the widespread failures of the Finned Tibia Tray Optetrak TKR, Exactech's corporate knowledge of those failures, and Exactech's cover-up scheme.

19. Relator Brooks Wallace has over eight years' experience in the orthopedic device industry, including as an Exactech sales representative from 2011 to 2013 and owner and managing partner of Gulf Surgical Solutions, an Exactech distributorship covering Alabama and the Florida Panhandle from 2013 to January 2017. In this role and as partner of Relator Robert Farley, Relator Wallace has knowledge of the Finned Tibia Tray Optetrak TKR's failures and Exactech's attempt to conceal those failures through denial and cover-up. Based in the Birmingham office of Gulf Surgical Solutions, Relator Wallace was the personal sales representative for Exactech's largest volume surgeon in Alabama and the Florida panhandle – Dr. David Lemak. Dr. Lemak is an orthopedic surgeon at Grandview Medical Center in Birmingham, Alabama, where he has practiced medicine for nearly 20 years with an impeccable reputation. Relator Wallace witnessed first-hand Dr. Lemak's frustration with the mounting failures of the Optetrak TKR device. Relator Wallace witnessed roughly 50-60 Finned Tibia Tray Optetrak TKR devices Dr. Lemak implanted in his patients fail within five years of implantation, many failing within two years. Dr. Lemak was appalled and reported his complaints to Relator Wallace, who passed them on to Exactech. Due to Exactech's cover-up and false marketing of the device, Dr. Lemak could not have realized the Optetrak TKR would fail at the time that he implemented them into his patients, but when the devices began to fail a year or two later, Dr. Lemak strongly voiced his concerns. Ultimately, the failures represented a total failure rate of roughly 30-35% of the Optetrak TKR devices implanted by Dr. Lemak. In attempts to gain explanations and remedy the massive device failures, Relator Wallace served as the intermediary between Exactech and a livid Dr. Lemak. During this process, Relator Wallace witnessed first-hand Exactech's cover-up "playbook" – including: (1) the company's denial of responsibility; (2) assignment of blame to Dr. Lemak's surgical technique, followed by offers to

Dr. Lemak of sports medicine consulting agreements. Because of Dr. Lemak's deep concern for his patients and frustration at the inexplicable failures, he refused to let the issue go, repeatedly complaining to Exactech, demanding a remedy, and ultimately forcing Exactech to grudgingly acknowledge some of the blame for the failures. After Relator Wallace explained to Exactech that Dr. Lemak was not satisfied with any of Exactech's explanations or excuses, he was told that they would not give up any information "that could hurt the company." Exasperated, Dr. Lemak ultimately refused to use any of Exactech's products in the future.

20. Relator Robert Farley has over 15 years of experience in the orthopedic device industry, including as an Exactech sales representative in 2012 and owner of Gulf Surgical Solutions, an Exactech distributorship covering Alabama and the Florida Panhandle from 2013 to January 2017. In this role and as partner of Relator Brooks Wallace, Relator Farley has knowledge of Exactech's products, corporate structure, reports of Finned Tibia Tray Optetrak TKR failures and Exactech's response to such failures including denials of liability and attempts to diffuse any push-back from surgeons by offering them phony consulting contracts. Relator Farley has discussed the Finned Tibia Tray Optetrak TKR failure with numerous other Exactech Distributors and Sales Representatives. Through these conversations, Relator Farley learned that the Finned Tibia Tray Optetrak TKR failures were widespread and that multiple other Distributors reported these failures to Exactech's corporate leadership; yet each Distributor received the same response: that each set of reported failures was the only instances of failure of which Exactech was aware and that it wasn't the device that was flawed but the individual surgeon's "flawed technique."

21. Defendant Exactech, Inc. is a manufacturer of orthopedic implant devices and related surgical instrumentation.

22. Prior to filing this Complaint, Relators voluntarily disclosed to the United States the information upon which this action is based. To the extent that any public disclosure has taken place as defined by 31 U.S.C. §3739(e)(4)(A), Relators are the original source of the information for purposes of that section. Alternatively, Relators have knowledge that is independent of and materially adds to any purported publicly disclosed allegations or transactions, and Relators voluntarily provided such information to the Government before filing this Complaint. Relators are serving contemporaneously herewith a statement of the material evidence in their possession upon which their claims are based.

I. APPLICABLE LAW

A. The Federal False Claims Act

23. The Federal False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733, provides, *inter alia*: any person who (1) "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval,"; (2) "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim,"; (3)"knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government" or (4) conspires to commit a violation of the False Claims Act is liable to the United States for a civil monetary penalty of not less than $5,500 and not more than $11,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104–410 [1]), plus treble damages. 31 U.S.C. § 3729(a)(1)(A), (B), (C), (G).

24. Under the FCA, (1) the terms "knowing" and "knowingly"— (A) mean that a person, with respect to information— (i) has actual knowledge of the information; (ii) acts in deliberate

ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and (B) require no proof of specific intent to defraud.

25. The FCA also defines the term "claim" as — (A) any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that— (i) is presented to an officer, employee, or agent of the United States; or (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government— (I) provides or has provided any portion of the money or property requested or demanded; or (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded; [] . 31 U.S.C. § 3729(b)(1)-(2).

B. The Anti-Kickback Statute

26. The Anti-Kickback Statute provides, *inter alia*:

> (1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind— (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.
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> (2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person— (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b).

27. With respect to violations of the Anti-Kickback Statute, a person need not have actual knowledge of this section or specific intent to commit a violation of this section. 42 U.S.C. §1320a-7b(h).

28. A payment violates the Anti-Kickback Statute if "one purpose of the payment was to induce" the furnishing medical products for which payment may be made in whole or in part under a Federal health care program, "even if the payments were also intended to compensate for professional services." *U.S. v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989) citing *United States v. Greber,* 760 F.2d 68, 69 (3d Cir.1985),

29. The provisions of the Patient Protection and Affordable Care Act, Publ. L No. I 11-148, 124 Stat.119 § 6402(f)(1) (2010) ("PPACA"), adopted on March 23, 2010, provide that: "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for the purposes of [the False Claims Act]."

C. The Securities Exchange Act of 1934 and Its Implementing Regulations

30. The Securities and Exchange Act of 1934 prohibits publicly traded companies and their representatives from making false or misleading statements to the investing public.

31. In particular, the Securities and Exchange Act, as enforced by the Securities and Exchange Commission (SEC), finds persons (defined to include corporations and associations existing under or authorized by the laws of the United States, 15 U.S.C. § 7) liable for making or causing to be made any false or misleading statement with respect to any material fact that causes others, in reliance upon such statement, to have purchased or sold a security at a price

which was affected by such statement for damages caused by such reliance. *See* 15 U.S.C. § 78r, *et al*.

32. Further, the SEC deems it unlawful "(b) [t]o make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading or (c) [t]o engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security." 17 C.F.R. § 240 (10b-5).

33. The SEC enforces other statutory and regulatory requirements to prosecute false and misleading statements made to the investment community, *see e.g*., Investment Advisors Act of 1940 § 207.

D. Exactech Deferred Prosecution Agreement and Corporate Integrity Agreement

34. For much of the time Exactech utilized consulting agreements to hush and bribe orthopedic surgeons, Exactech was bound by and thus violated a Department of Justice Deferred Prosecution Agreement and Corporate Integrity Agreement.

35. On December 2, 2010, Exactech agreed to a 12-month Deferred Prosecution Agreement stemming from a criminal complaint in the District of New Jersey that Exactech conspired to violate the Anti-Kickback Statute.[1] Specifically, the criminal complaint at issue alleged that Exactech entered into consulting agreements with orthopedic surgeons that were designed and implemented to induce the surgeons to use, and cause the purchase of, Exactech's hip and knee reconstruction and replacement products.[2]

36. In a collateral civil case, Exactech reached a civil settlement with the Department of Justice and the U.S. Department of Health and Human Services, Office of Inspector General

[1] United States of America v. Exactech, Inc. Deferred Prosecution Agreement (Dec. 2, 2010)
[2] United States of America v. Exactech, Inc. Crim No. 10-837, Criminal Complaint at ECF 1. (Dec. 7, 2010) (D.N.J.)

(HHS-OIG) to pay $2.99 million and enter a Corporate Integrity Agreement to settle government claims that the company's fraudulent marketing practices caused false claims to be submitted to the federal Medicare program in violation of the FCA.[3]

37. By the terms of the Exactech Corporate Integrity Agreement, Exactech was required to develop and implement an extensive set of policies and procedures to specifically address compliance with the Anti-Kickback Statute.[4]

38. The Corporate Integrity Agreement further required Exactech to disclose "Reportable Events," defined as "anything that involves: a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized," to HHS-OIG.[5]

39. Further, Exactech was required to submit an Implementation Report, detailing its compliance program and Annual Reports of the Corporate Integrity Agreement detailing its ongoing compliance with its Corporate Integrity Agreement obligations. The Implementation Report and each Annual Report required certifications by the Exactech Compliance Officer that Exactech was in compliance with all requirements of the Corporate Integrity Agreement.[6]

40. By refusing to disclose the known products defects of the Exactech Optetrak TKR device, in violation of criminal, civil and administrative laws applicable to Federal health care programs and offering, and not disclosing, illegal remuneration to induce continued use of its products, Exactech systematically violated the Corporate Integrity Agreement and made a mockery of the leniency afforded to it by a self-administered compliance plan.

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[3] Corporate Integrity Agreement Between Office of Inspector General of the Department of Health and Human Services and Exactech, Inc. (Dec. 7, 2010)
[4] *Id.*
[5] *Id.* at p. 17
[6] *Id.* at p. 23-24

E. Government Health Care Programs

1. The Medicare Program

41. Under Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395, *et seq*., the United States provides health insurance coverage for eligible citizens, known commonly as "Medicare." The United States Department of Health and Human Services, specifically the Center for Medicare and Medicaid Services ("CMS") oversees the administration of Medicare.

42. The Medicare Program operates two separate programs. Medicare Hospital Insurance Benefits for the Aged and Disabled – commonly referred to as "Medicare Part A" – entitles beneficiaries to, among other things, in-patient hospital services and post-hospital extended care services. 42 U.S.C. § 1395d. The costs of TKR surgery related to the in-patient care including the cost of the implant device and a patients' in-patient hospital stay are covered under the provisions of Medicare Part A. *Id.* Medicare also provides Supplementary Medical Insurance Benefits for the Aged and Disabled, referred to as "Medicare Part B." Medicare Part B covers a wide range of medical services and supplies such as those furnished by physicians or others in connection with physicians' services, outpatient hospital services, outpatient physical therapy and occupational therapy services, and home health services. Physicians' services covered under Part B include visits to patients in the home, office, hospital, and other institutions. Part B also covers certain drugs and biologicals that cannot be self-administered, diagnostic x-ray and laboratory tests, purchase or rental of durable medical equipment, ambulance services, prosthetic devices, and certain medical supplies. 54 Fed.Reg. 4302, 4303–04 (Jan. 30, 1989). Included in these payments are the outpatient and physical therapy portions of a patient's care related to TKR surgery. 42 U.S.C. § 1395k.

43. It is a universal requirement of the Medicare program that all items and services provided

to Medicare beneficiaries must be reasonable and medically necessary. *See* 42 U.S.C. §1395y(a)(1)(A). It is axiomatic that the government controls Medicare costs by denying coverage claims for items or services that are not "reasonable and necessary" for treatment. *International Rehabilitative Sciences Inc. v. Sebelius*, 688 F.3d 994, 997 (9th Cir. 2012) citing 42 U.S.C. §1395y(a)(1)(A). "A device is not 'reasonable and necessary' – and thus is not eligible for Medicare coverage – if it is not 'safe' and 'effective' – that is, if the device has not 'been proven safe and effective based on authoritative evidence' or is not 'generally accepted in the medical community as safe and effective for the condition for which it is used.'" *Id.*; 54 Fed.Reg. 4302, 4303–04 (Jan. 30, 1989).

2. The Federal/State Medicaid Programs

44. Medicaid is a joint federal-state program that provides health care benefits for certain groups, primarily the poor and disabled. The federal portion of each state's Medicaid payments varies by state and is generally between 50 and 83 percent, depending on the state's per capita income. 42 U.S.C. § 1396d(b). Most states' definition of medical necessity mirrors that of the Federal Medicare definition. For example, according to the Florida Medicaid Agency:

> 'Medically necessary' or 'medical necessity' means that the medical or allied care, goods, or services furnished or ordered must:
> (a) Meet the following conditions:
> 1. Be necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain;
> 2. Be individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the patient's needs;
> 3. Be consistent with generally accepted professional medical standards as determined by the Medicaid program, and not experimental or investigational;
> 4. Be reflective of the level of service that can be safely furnished, and for which no equally effective and more conservative or less costly treatment is available; statewide; and
> 5. Be furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

> (b) "Medically necessary" or "medical necessity" for inpatient hospital services requires that those services furnished in a hospital on an inpatient basis could not, consistent with the provisions of appropriate medical care, be effectively furnished more economically on an outpatient basis or in an inpatient facility of a different type.
>
> (c) The fact that a provider has prescribed, recommended, or approved medical or allied care, goods, or services does not, in itself, make such care, goods or services medically necessary or a medical necessity or a covered service.

Florida Administrative Code (Rule 59G-1.010).

3. The TRICARE Program

45. TRICARE is a managed health care program established by the Department of Defense. 10 U.S.C. §§ 1071-1110. TRICARE provides health care benefits to eligible beneficiaries, which include, among others, active duty service members, retired service members, and their dependents. 32 CFR 199.17(a)(6)(i).

46. The regulatory authority establishing the TRICARE program excludes from coverage services and supplies that are not medically necessary. *See* 32 C.F.R. § 199.4(g)(1). Specifically, medical devices for which the safety and efficacy of which have not been established cannot be paid for by the TRICARE program. *See* 32 C.F.R. § 199.4(g)(15). This exclusion includes all services directly related to the device. 32 C.F.R. § 199.4(g)(15)(iii).

4. The Federal Employee Health Benefits Program

47. The Federal Employee Health Benefits Program ("FEHBP") is a federally-funded health care program established by Congress in 1959, pursuant to the Federal Employees Health Benefits Act. 5 U.S.C. §§ 8901, *et seq*.

48. The Office of Personnel Management ("OPM") administers this program and contracts with various health insurance carriers to provide services to FEHBP members. *Id*. at §§ 8902, 8909(a).

49. Monies for the FEHBP are maintained in the Employees Benefits Fund ("Treasury Fund"), which OPM administers. *Id*. at § 8909(a). The Treasury Fund – which the United States Treasury holds and invests – is the source of all relevant payments to the insurance carriers for services rendered to members. *Id*. at § 8909.

5. The Veterans Administration

50. The Veterans Administration (VA) maintains a system of medical facilities that provide Veterans with medical care, including TKR surgeries. The VA operates by purchasing medical supplies such as knee replacement implants directly from device manufacturers through the Federal Supply Schedule (FSS). Medical equipment and supplies contracts, such as knee replacement devices are governed by the Federal Supply Schedule Group 65, Part II, Section A.

51. From April 1, 2008 (the date Exactech had definitive knowledge the Finned Tray was defective) to January 1, 2018, Exactech completed 1,580 separate VA contracts.[7]

52. The largest of which, Contract Number V797P4299A, was a five-year $2,228,280 contract for the delivery of Medical Equipment and Supplies, consisting of hundreds of Primary Knee Replacements and revision knee surgeries.[8] Exactech performed the contract from February 15, 2007 to March 31, 2012.[9] Throughout the majority of that time period, Exactech knew the Finned Tibia Tray was defective, yet continued to supply the Finned Tray to the VA.[10] Accordingly, Exactech continued to sell, directly to the VA, faulty medical devices to be surgically implanted into United States veterans.

53. Exactech has many of its products available for sale to the VA through the FSS and conducts a significant volume of business selling knee replacement implants, including the

[7] http://government-contracts.insidegov.com/d/d/Exactech%2C-Inc-..-
[8] http://government-contracts.insidegov.com/l/8117447/V797P4299A
[9] http://government-contracts.insidegov.com/l/8117447/V797P4299A
[10] http://government-contracts.insidegov.com/l/8117447/V797P4299A

Finned Tibia Tray Optetrak TKR. For instance, in the 2016 VA FSS, the known to be defective Finned Tibial Tray was available for sale to the VA at a price of $1,118.02.[11] The total cost of an Optetrak TKR device, to the VA under this contract if the Finned Tibia Tray was selected, would be between $4,143.88 to $4,487.33, depending upon which femoral component was used and this VA price could be greater if the patient needed additional hardware.

54. Relators have knowledge that Exactech sold a significant number of Finned Tibia Tray Components to VA hospitals.

F. Government Regulation of Medical Devices

55. The Medical Device Amendments of 1976, 21 U.S.C. § 360c *et seq*. amended the Food Drug and Cosmetic Act ("FDCA") to "provide for the safety and effectiveness of medical devices intended for human uses." Pub. L. No. 94-295, 9 Stat. 539, 53 (May 28, 1976) (preamble). The Medical Device Amendments provided the FDA greater authority to regulate medical devices and to prevent devices lacking evidence of safety and effectiveness from being marketed in the United States.

56. The Medical Device Amendments established three classes of medical devices; Class I, Class II, and Class III. 21 U.S.C. § 360c.

57. As a "knee joint patellofemorotibial polymer/metal/polymer semi – constrained cemented prosthesis intended to replace a knee joint," the Exactech Optetrak TKR is classified as a Class II device. *See* 21 CFR 888.3560.

58. The Medical Device Amendments denote Class II devices as requiring "special controls" "because the general controls by themselves are insufficient to provide reasonable assurance of

[11] Tryco Incorporated; Authorized FSS Price List; Contract: V797-P-49-64a; available at: https://www.gsaadvantage.gov/ref_text/V797P4964A/0PGOK2.3AGIBQ_V797P-4964A_V797P4964A02012016.PDF (last visited January 23, 2018)

the safety and effectiveness of the device, and…there is sufficient information to establish special controls to provide such assurance, including the promulgation of performance standards, postmarket surveillance, patent registries, development of dissemination of guidelines…recommendations, and other appropriate actions as the Secretary deems necessary to provide such assurance." 21 U.S.C. § 360c.

59. These special controls focus on the obligations of device manufacturers and importers to report problems with its marketed devices to the FDA.

60. One area of post-market surveillance special controls is the Medical Device Reporting (MDR) requirements, defined in 21 CFR § 803, as authorized by Section 519 of the Federal, Food, Drug and Cosmetic Act (FD&C Act). "The MDR regulation provides a mechanism for the Food and Drug Administration (FDA) and manufacturers to identify and monitor significant adverse events involving medical devices. The goals are to detect and correct problems in a timely manner. While the requirements of the regulation can be enforced through legal sanctions [including seizure, injunction, civil money penalties, and criminal prosecution][12] authorized by the Federal Food, Drug and Cosmetic (FD&C) Act, ***FDA relies on the goodwill and cooperation of all affected groups to accomplish the objectives of the regulation***."[13] (emphasis added)

1. Mandatory Reporting Regulations, Which Were Violated

61. Specifically, the Medical Device Amendments require a device manufacturer to submit initial and supplemental reports to the FDA no later than 30 calendar days after the day that the

[12] Medical Device Reporting for Manufacturers. Guidance for Industry and Food and Drug Administration Staff. U.S. Department of Health and Human Services. Food and Drug Administration, Center for Device and Radiological Health. November 8, 2016. Available at: https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm359566.pdf

[13] Medical Device Reporting for Manufacturers. Guidance for Industry and Food and Drug Administration Staff. U.S. Department of Health and Human Services. Food and Drug Administration, Center for Device and Radiological Health. March 1997. Available at https://ntrl.ntis.gov/NTRL/dashboard/searchResults/titleDetail/PB99105421.xhtml

manufacturer "receives or otherwise becomes aware of information, from any source, that reasonably suggests that a device that [the manufacturer] market(s): (A) may have caused or contributed to a death or serious injury, or (B) has malfunctioned and that such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur." 21 CFR § 803.50; 21 U.S.C. § 360i.

62. The MDR Requirements contain specific definitions that are pertinent to understanding when and what a device manufacturer must report to the FDA. Some of these definitions include:

A. "Medical Device": "An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is…intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. § 321.

B. "Manufacturer": "any person who manufacturers, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedure. The term includes any person who either…Manufacturers components or accessories that devices that are ready to be used and are intended to be commercially distributed and intended to be used as is, or are processed by a licensed practitioner or other qualified person to meet the needs of a particular patient." 21 CFR § 803.3(l).

C. "Become aware" means "that an employee of the entity required to report has acquired information that reasonably suggests a reportable adverse event has occurred." 21 CFR § 803.3(b).

D. "Serious Injury": "an injury or illness that…results in permanent impairment of a body function or permanent damage to a body structure or Necessitates medical or surgical intervention to preclude permanent impairment of function or permanent damage to a body structure." 21 CFR § 803.3(w).

E. "Remedial action" means any action other than routine maintenance or servicing of a device where such action is necessary to prevent recurrence of a reportable event." 21 CFR § 803.3(v).

63. When a manufacturer learns of such an adverse (or "reportable") event, such as a Total Knee Replacement Revision surgery, the manufacturer must submit the following information: (i) any information that the manufacturer can obtain by contacting a user facility, importer or

other initial reporter; (ii) any information in the manufacturer's possession; and (iii) any information that the manufacturer can obtain by analysis, testing, or other evaluation of the device. 21 CFR § 803.50(b)(1). The manufacturer is responsible for conducting an investigation of each event and evaluating the cause of the event. 21 CFR § 803.50(b)(3).

64. These reporting requirements are ongoing; if a manufacturer later obtains any required information that was not available at the time the manufacturer filed its' initial report (assuming, of course, the manufacturer complied with its' affirmative obligation to file an initial report), the manufacturer must submit this information in a supplemental report. 21 CFR § 803.50(b)(3).

65. The MDR Requirements have developed Form FDA 3500A which provide the discrete categories of information required to be submitted with an individual adverse event report. Form FDA 3500A requires the manufacturer to submit, among numerous categories of other information: specific patient information, description of the event or problem, including a discussion of how the device was involved, patient outcomes attributed to the adverse event, date of implantation and explantation, patient follow-up or required treatment, any environmental conditions that may have influenced the event and identifying and contact information of the reporter who informed the device manufacturer. 21 CFR § 803.52. If a Form 3500A report omits any required information, the manufacturer must explain why this information was not provided and the steps taken to obtain this information. *Id.*

66. By collecting this information, the FDA uses Medical Device Reports (MDRs), including the mandatory Adverse Event Reports, to detect potential device-related safety issues and contribute to benefit-risk assessments of medical devices.[14]

[14] U.S. Food & Drug Administration MAUDE – Manufacturer and User Facility Device Experience, available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm (last visited January 18, 2018)

67. To educate physicians and the public of potential dangers and risks of certain devices, the FDA publishes Adverse Event Reports to its Manufacturer and User Facility Device Experience ("MAUDE") database. 21 CFR § 803.9. The MAUDE database houses MDRs submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers.

2. Remedial Action

68. The information referenced above pertains to what is commonly referred to as a "30 day report" due to the 30 day deadline with which to submit such information. However, the MDR also requires device manufacturers to submit a more serious and thus more time sensitive "5-day report" – containing similar information – within "5 work days after the day that the manufacturer becomes aware that: (a) An MDR reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health." 21 CFR § 803.53. This requirement emphasizes that a manufacturer "may become aware of the need for remedial action from any information, including any trend analysis." 21 CFR § 803.53.

69. If Manufacturers undertake remedial or corrective action such as correcting a device – and the correction was initiated to reduce a risk to health posed by the device or to remedy a violation of the FDCA caused by the device which may present a risk to health – the manufacturer shall submit a written report to the FDA of any correction or removal within 10-working days of initiating such correction or removal. 21 CFR § 806.10.

3. Medical Device Manufacturer Duty to Issue Recalls

70. "Recall is a voluntary action that takes place because manufacturers and distributors carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective." 21 CFR §7.40(a). Recall may be

undertaken voluntarily and at any time by manufacturers and distributors, or at the request of the Food and Drug Administration. 21 CFR §7.40(b). A request by the Food and Drug Administration that a firm recall a product is reserved for urgent situations. *Id.*

71. The FDA may request a firm to initiate a recall when the following determinations have been made: (1) That a product that has been distributed presents a risk of illness or injury or gross consumer deception; (2) That the firm has not initiated a recall of the product; and (3) That an agency action is necessary to protect the public health and welfare. 21 CFR §7.45.

72. However, in order for the FDA to make such determinations to request a recall or pursue other enforcement action, it must be assumed that the FDA has knowledge of the risk of injury, gross consumer deception, or danger to public health and welfare. Thus, for the FDA to have such knowledge and to achieve the FDCA's goals to provide for the safety and effectiveness of medical devices, the FDA relies on device manufacturers to adhere to their mandatory duties to report adverse events and corrective actions.

II. Total Knee Replacement Surgery Background

A. Primary TKR

73. TKR surgery is a major orthopedic operation that has become one of the most common and generally successful orthopedic procedures in the United States. TKR operations are typically performed when a patient's knee joint has significantly deteriorated causing chronic knee pain and disability. The most common cause of such deterioration is osteoarthritis, the primary diagnosis for 87% of TKR procedures, and is primarily due to age-related "wear and tear." Osteoarthritis causes the cartilage that cushions the bones of the knee to soften and wear away. Without this cartilage, the bones, femur (thigh bone), and tibia (large shin bone) connected to the knee joint rub together causing knee pain and stiffness and can lead to

immobility. Often, a patient's knee pain due to osteoarthritis reaches a point where it becomes difficult to walk, knee pain persists day and night even while resting, and the knee is chronically inflamed and may bow in or outward. At this point, patients often resort to knee replacement surgery.

74. The procedure involved in a primary TKR – or a patient's first TKR surgery – generally consists of the following steps wherein the surgeon must (1) make an incision into the patient's knee area and prepare the bone – which requires the damaged cartilage surfaces at the ends of the femur and tibia to be removed along with a small amount of underlying bone; (2) the surgeon must then use a sizer tool that is unique to each model and brand of implant to accurately measure the patient's bones and the space available to insert the metal implants and decide on an appropriate size of implant to use (the sales representative for the particular implant company is in the operating room with a primary set and back-up set of all possible size combinations of implants); (3) normally and with Exactech products, acrylic bone cement is placed on both the prosthetic components and the patient's bone and the surgeon fits the metal components into the patients' bone; (4) the surgeon then uses a large mallet to hammer the metal components snugly into the space in which the implant will sit within the carved out area of bone; (4) the surgeon typically then holds the particular portion of the leg in place for roughly 30 seconds while the fast-curing heated cement bonds the implant to the bone – the bone cement cures within four to ten minutes of implantation; (5) finally, the surgeon inserts a plastic polyethylene spacer ("poly") between the femoral component and the tibia component to serve as a cartilage replacement and prevent the components from rubbing against each other.

75. TKR surgery has become increasingly prevalent. A study conducted in 2007 estimated that over 700,000 TKR surgeries were performed annually in the United States and estimated

that the number of primary TKR surgeries is projected to grow steadily and reach 3.48 million annually (a growth rate of 673%) by 2030.[15] This growth in projected TKR surgeries is believed to result from the aging of the "baby boomer" generation, higher rates of diagnosis and treatment of advanced arthritis, and growing demand for improved mobility and quality of life.[16] Experts believe these factors will make joint replacements the most common elective surgical procedures in the coming decades.[17] Not only are more TKR surgeries being performed each year but trends of (a) younger individuals increasingly receiving joint replacements and (b) improvements in life expectancy have created a large pool of individuals living with knee replacements in the United States. In 2010, there were over 4.7 million individuals in the U.S. living with at least one knee replaced. As noted above, there are strong trends showing that the incidence of TKR surgeries is rising; however assuming there is no further rise in incidence, the aging of the country's population alone would result in an estimated 7.4 million individuals in the United States living with at least one replaced knee in 2030.[18]

76. Because the conditions that lead to a patient having a TKR – namely osteoarthritis – primarily impact the elderly, over 60% of TKR surgeries are performed on patients over the age of 65.[19] A typical elderly patient undergoing a major surgical operation incurs significant attendant healthcare costs, including an average 4.2 day in-patient hospital stay (this estimate is

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[15] Kremers, Hilal Maradit et. al. Prevalence of Total Hip and Knee Replacement in the United States; The Journal of Bone and Joint Surgery, Volume 97, Issue 17. 1386-1397 (Sepember 2, 2015) Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4551172/

[16] *Id.*

Id.

[18] *Id.*

[19] Li, Yu; et al. Variation of Medicare payments for total knee arthroplasty; The Journal of Arthroplasty Volume 28, Issue 9, 1513-1520 (October 2013). Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3795823/

for Primary TKR patients who receive the Exactech Optetrak system specifically)[20], follow-up visits and extensive outpatient rehab and physical therapy.

77. In 2009, 227,587 Medicare beneficiaries received a Primary TKR and the average Medicare payment for only the in-patient portion of the procedure (including the implant) was $13,464.[21] By 2015, 431,199 patients covered by traditional Medicare underwent knee replacement surgery. In-patient costs for Primary TKR procedures had risen to over $19,000 by 2012/2013 timeframe.[22]

B. Revision TKR

78. If a patient who already received a primary TKR experiences problems with that operation or implant, such as a device malfunction or device failure, then it may be necessary to perform a "Revision TKR." Revision TKR is a much more intensive operation than a Primary TKR as the intra-operational procedures are more complex to remove the Primary TKR and insert the Revision TKR implant – which is a different model of implant specific to Revision TKRs that is larger, heavier and requires removal of more of the patient's bone and more cement to affix the implant to the patient's remaining bone.

79. Due to increased severity of a Revision TKR, the cost of Revision TKR procedures is greater than the cost of Primary TKR procedures. In 2009, the average Medicare payment for Revision TKR was $17,331, nearly 30% greater than average reimbursement for a Primary TKR. Further, as they are more complicated cases, seven percent of 2009 Medicare Revision TKR

[20] Edwards J, Gradisar I Jr, Nadaud M, Kovacik M, Askey M. Eight and one-half year clinical experience with the Optetrak total knee prosthesis. Presented at the American Academy of Orthopaedic Surgeons. February 2004

[21] *Id.*

[22] Weeks, William B.; et al. Episode-of-Care Characteristics and Costs for Hip and Knee Replacement Surgery in Hospitals Belonging to the High Value Healthcare Collaborative Compared with Similar Hospitals in the Same Health Care Markets. Medical Care Volume 55, Number 6 (June 2017). Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5432098/

cases triggered Medicare "outlier" payments, which were $10,000 or higher per case beyond regular diagnosis-related group payments. These "outlier" payments occurred in less than one percent of primary TKR cases.[23] Similar to Primary TKR procedures, Medicare is by far the largest payor of Revision TKR operations and attendant inpatient and outpatient costs – in a sample of Revision TKR operations conducted in 2005-2006, Medicare was the primary payor for 59.5% of revision TKR procedures.[24]

80. These greater costs include a more expensive implant. Exactech's Optetrak Revision tibia tray costs between $1300-2000 whereas the Optetrak Finned Tray used in Primary TKR costs roughly $1,100. The added complexity and scope of Revision TKR procedures almost always result in a longer hospitalization period and longer and more significant outpatient recovery. Further, the more substantial surgical procedure and more cumbersome implant used in Revision TKR significantly limits the patient's range of motion and mobility as compared to a Primary TKR.

81. One of the most common reasons that a Primary Knee Replacement device can fail and then must be replaced in a Revision procedure is if the tibia component of the TKR device becomes loose – referred to as a "tibial loosening." When "tibial loosening" or "aseptic" loosening occurs the keel of the tibia tray which is anchored to the patient's tibia becomes loose and wobbles at the point of contact where the mechanical knee meets the patient's bone structure. Tibial loosening is often very painful and even dangerous when a patient simply puts

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[23] Li, Yu; et al. Variation of Medicare payments for total knee arthroplasty; The Journal of Arthroplasty Volume 28, Issue 9, 1513-1520 (October 2013). Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3795823/

[24] Bozic, Kevin J.; et al The Epidemiology of Revision Total Knee Arthroplasty in the United States, Clinical Orthopedics and Related Research. Volume 468, Issue 1 pg. 45-51 (January 2010) available at: https://link.springer.com/article/10.1007/s11999-009-0945-0

weight on her knee. Tibial loosening can also lead to infection as the implant unintentionally moves within the patient's knee.

C. Average Revision Rates of Cemented Total Knee Replacements

82. "Revision surgery remains the benchmark outcome by which survival of orthopedic implants is assessed."[25] Most aggregate data that allows for assessment of the rate of TKR revision surgeries is found in National Joint Registries. Eleven countries maintain mandatory National Joint Registries and track every orthopedic device and its' outcomes, including The United Kingdom, Sweden, New Zealand and Australia. Orthopedic groups in the United States have recently taken strides to establish a national joint registry and published its first annual report in 2013. However, reporting to the American Joint Replacement Registry is voluntary and thus does not capture an encompassing view of joint replacement procedures.

83. Established National Joint Registries demonstrate that a risk of revision surgery following a primary Total Knee Replacement for Osteoarthritis (the diagnosis encompassing over 83% of Primary TKRs) at 10 years post-operatively is roughly 5%.[26] Therefore, a revision rate of 5%, or correspondingly a 95% survival at 10 years is viewed as industry standard among orthopedic device manufacturers.

84. At five years post-operatively, the standard rate of revision for Primary TKA for patients that underwent the primary surgery in 2008 was 3%.[27] In other words, 97% of Primary TKA devices are expected to remain in good working order and not require a Revision TKR within the first 5 years.

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[25] M. Khan, et al. The epidemiology of failure in total knee arthroplasty: Avoiding Your Next Revision. *Bone Joint J* 2016;98-B (1 Suppl A):105-12

[26] *Id.*

[27] *Id.*

85. Further, over 90% of modern TKR devices are still functioning well 15 years after the primary surgery.[28] Accordingly, the Optetrak Finned Tray Primary TKR represents a startling outlier with its tibia tray failing and resulting in a Revision TKR in 1 out of every 3 surgeries performed within three years.

86. Relator Manuel Fuentes has in-depth knowledge of the industry standards of orthopedic device survival rates and believes that any total knee replacement device with a revision rate of more than five percent at five years post-operatively would signal that the device has some type of innate problem or design defect. He further believes, from his experience throughout his career and specifically issuing a product recall on an orthopedic device with another orthopedic company, that when revision rates of greater than five percent at five years post-operatively occur, the company has a duty to alert the FDA and likely issue a recall.

III. **Exactech's History and the Optetrak TKR**

87. As noted above, Exactech was founded by Dr. William Petty, M.D., an orthopedic surgeon and Dr. Gary J. Miller, PhD, a biomedical engineer. Part of Exactech's intra-company lore is the humble roots from which Drs. Petty and Miller started Exactech. Both Drs. Petty and Miller were frequent consultants for major orthopedic device companies but believed they would be better suited to start their own orthopedic device company. Dr. Petty bemoaned that the major medical device companies did not adequately understand and account for the issues that real-world surgeons encounter in the operating room. Similarly – as company lore goes – Dr. Miller felt medical device companies for whom he worked as a consultant were too focused on the financial aspects of device engineering and manufacturing which inhibited his preferred designs.

[28] American Academy of Orthopedic Surgeons, Total Knee Replacement available at: http://orthoinfo.aaos.org/PDFs/A00389.pdf

Because of their shared grievances, the surgeon and the engineer decided to start their own orthopedic device company – Exactech.

88. Dr. Petty and Dr. Miller embarked on a mission designed to be "surgeon focused, patient driven" – as the Exactech motto proclaims. In the context of Total Knee Replacements, which has been Exactech's primary implant and driving force of the company since its inception, this "surgeon focused, patient driven" ideal meant developing implants that would give surgeons more flexibility in the size of Total Knee Replacement components.

89. Most Total Knee Replacement implants have three primary components that affix to the patients' bone structure. One piece, the femoral component, is affixed to the patient's femur as it anchors the implant to the femur bone above the patient's knee. Another piece, the tibial component (or tibial tray), is affixed to the patient's tibia below the knee. This single tibia component typically and in Exactech's TKR models features a down stem (also referred to as a "keel"), which is hammered (or "set"), then cemented into the tibia and a flat tray the cartilage replacement made of a hard-plastic polymer ("poly") sits upon. The final piece is the patella component which covers the poly insert and joins the femoral and tibial components.

90. As the bone structure and size of knee replacement patients can be quite variable, different sizes of the femoral component and the tibia tray are required to appropriately fit the size of an individual patient's bones. The industry standard is for an orthopedic company to offer six different sizes of TKR components, commonly denoted as size one through size six – size one being the smallest and size six being the largest. For example, a small, slight female patient would be a candidate for the smaller sizes of femoral components and tibia tray – likely a size one or two, whereas a tall, larger male patient would be a candidate for the larger sized femoral component and tibia tray – likely a size five or six.

91. Exactech – led by Drs. Petty and Miller – believed that providing the surgeon with a variety of options was key to best fitting the correct size femoral and tibial components to a particular patient. To provide such options Exactech designed its' TKR to allow surgeons to size the femoral component and the tibial tray component independently. Because the sizes of the tibial and femoral components should be relatively similar – Exactech and other orthopedic companies only allow deviation in tibia size to femoral size to be the difference of one full size up or down. While independently sized femoral and tibial components was not a major departure from other orthopedic implant companies, previously companies sized the tibia first then sized the femur to match or potentially deviate by one size. This is important because the tibial component endures far greater stress once implanted than the femoral component and is far more likely to be the component that wears away first or fails, requiring a revision. However, because Exactech wanted to design its' TKR with an ultra-congruent fit between the femur and poly insert, Exactech reversed the traditional sizing procedure, placing more emphasis on the femoral component and then adjusting the tibial component to fit.

92. One of the primary grievances that Drs. Petty and Miller had with their previous consulting clients was that these companies refused to pursue designed TKR models that would allow for independently sized femur and tibia components. These companies refused to embark on such an experimental path for several reasons but notably that such mismatched sizes would require the device manufacturer to invest in and carry a huge amount of inventory in order to have the required implant for each possible size combination in each surgical situation. For instance, Exactech's complex mismatched inventory system required its reps to attend surgeries with 15 possible tibia sizes and 60 polyethylene inserts, whereas most orthopedic companies only required six tibia component sizes and 24 polyethylene inserts.

93. Dr. Albert Burstein, PhD, who helped develop the Insall-Burstein Prosthesis is a renowned scientist who served as Director of Biomechanics, Research Division at the Hospital for Special Surgery in New York, New York from 1976 to 1992 and Senior Scientist with the Hospital of Special Surgery until 1996. Notably, in his later years at the Hospital for Special Surgery, in 1994, the same year the Optetrak TKR was released, Dr. Burstein created Brighton Partners, Inc., a company that has been Exactech's sole supplier of plastic polyethylene bearings used as the cartilage replacement in the Optetrak TKR system since the introduction of the Optetrak TKR.

94. Dr. Burnstein is also a credited designer of the Optetrak system and the Finned Tibia Component. Relators have knowledge that Dr. Burnstein advised Exactech the Finned Tibia Component was too thin – which would lead to tibia loosening problems – yet was rebuffed by Exactech. In 2010, Dr. Burstein was presumably no longer interested in being an owner of Exactech's external sole source supplier of the polyethelene inserts, and Exactech purchased Brighton Partners Inc. in an all-cash transaction for $5.5 million.[29]

A. Exactech's Optetrak Products

95. The Optetrak TKR system was released in 1994 and has been Exactech's the largest product line since the company began selling orthopedic implants. In 2007, Exactech's Knee Division accounted for $63.4 million of the company's total revenue of $124.2 million, or 51% of total revenue. Within the Optetrak product line, Exactech only had two options for tibia trays until 2011 – the defective Finned Tibia Tray and the "Trapezoid" Tray, which was used as the revision system.

[29] https://www.news-medical.net/news/20100525/Exactech-acquires-Brighton-Partners.aspx

96. Having only one product line with only one Primary Knee Tibia Tray (and only one Revision Tibia Tray model) is an extremely narrow product line and a significant aberration from standard orthopedic device industry practice. For instance, Exactech's competitor Stryker has over a dozen different knee models from which to choose. A major reason that orthopedic implant companies have more than one product line for a given implant and typically multiple – interchangeable – components within that product line is because if the company realizes that there is a problem with a component or even a particular product line, the company can remove the problematic component or product from the marketplace without destroying the company's entire revenue source.

97. This over-reliance on one component (the Finned Tibia Tray) within one product (Optetrak TKR) created an excessive risk situation beyond the standard business-risk confronting an orthopedic device company with a failing medical device which includes direct medical costs for affected patients, potential class action legal liability, significant reputational damage, loss of future business and R&D costs of a new product.

98. Exactech's excessive business risk was further amplified because of Exactech's mismatched implant sizing and high cost inventory strategy. Essentially, Exactech had put all of its' eggs in a very expensive basket and as went the Finned Tibia Tray so went Exactech. Based on this excessive risk, Exactech was particularly poorly positioned to deal with a potential recall – and ultimately determined that it would avoid a recall at all costs, even if that meant committing fraud.

99. Because of this excessive risk, when Exactech discovered that the Finned Tibia Tray Optetrak TKR was causing thousands of revision surgeries, and failing at rates more than 10 times the industry standard, it was a catastrophic problem for the company. When the issue

came up, Exactech distributor Timothy O'Neill summed it up best by saying: if Exactech would have complied with its' legal, ethical and moral obligations and disclosed the Finned Tibia Tray failures, "the stock price would have dropped to sixteen cents overnight."

IV. Exactech's Fraudulent Schemes

A. Early Reports of Finned Tibia Tray Optetrak TKR Failure

100. The first known and substantial disclosure to Exactech of widespread Finned Tibia Tray Optetrak TKR failure was in 2007 or early 2008 and believed to be from Exactech Distributor Timothy O'Neill, owner of Surgical Systems Inc. in Gorham, Maine and his primary orthopedic surgeon client, Dr. Wayne Moody. As explained to Relator Robert Farley, Dr. Moody – an orthopedic surgeon based in Auburn, ME – was the "keystone client" for Mr. O'Neill's company and began to complain to Mr. O'Neill that he was seeing an increasing number of patients experiencing significant tibial loosenings with the Finned Tibia Tray Optetrak TKR. Overall, Dr. Moody had 51 patients with tibial loosening problems due to the Finned Tibia Tray's device failure. Each of the 51 patients required a revision surgery and was disclosed to Exactech. This high number of failures was unprecedented in Dr. Moody's experience and upset him greatly. Accordingly, Mr. O'Neill and Dr. Moody made a detailed presentation – including an intra-operation film – to Exactech. Mr. O'Neill was then assured by Exactech that it would put together a "committee" to address the failures.

101. Exactech's response to Mr. O'Neill and to Dr. Moody (and effectively to the 51 patients whose knee replacement devices came loose and required a major secondary surgery) was that Dr. Moody was the only surgeon from whom they were hearing of these device failures and that the problem was not with the Finned Tibia Tray but instead with Dr. Moody's "cement technique."

102. Surprisingly, Dr. Moody remained a loyal customer of Exactech joint replacements despite 51 of his patients experiencing device failures and Exactech's attempting to blame Dr. Moody himself for the failures. The explanation for Dr. Moody's loyalty is that Exactech offered Dr. Moody a "consultant agreement." For instance, in 2012, Exactech paid Dr. Moody $11,870 for "Research/Clinical studies support."[30] Relators believe Dr. Moody received even more substantial consulting payments prior to 2012 and that the consulting agreements required little to no effort on Dr. Moody's part other than that he tacitly continue to use and stop complaining about the Optetrak TKR Finned Tibia Tray. Further, upon receiving complaints of tibial loosening from Dr. Moody, Exactech also hired Dr. Moody's son as an Exactech sales representative – further securing Dr. Moody's allegiance to Exactech through *qui pro quo* remuneration for Dr. Moody's silence and continued business.

103. Relators are aware of several other physicians whose patients experienced tibial loosenings requiring revision surgeries due to the Finned Tibia Tray's design defects and who reported these device failures to Exactech around this same time – most concentrated in the latter half of 2007. Randy Hebert, the largest Exactech distributor in the United States, based in Ocala, Florida and with sales territory throughout Florida, dealt with numerous surgeons who saw patients experience tibial loosening due to the design failures of the Finned Tibia Tray in the Optetrak TKR.

104. Mr. Hebert's territory is the largest volume territory in the United States – often selling more than $20 million annually in Exactech products. Despite the complaints from Mr. Herbert's physician clients, Exactech maintained to Dr. Moody that he was the only surgeon experiencing failures with the Finned Tibia Tray.

[30] http://exactech.co.jp/company/corporate-compliance/our-consultants/moody-wayne-md

105. Due to Mr. Hebert's large volume (in the most lucrative geographic area in the country for elderly, primarily Medicare, knee replacement patients) and long tenure as a distributor with Exactech, Mr. Hebert is often looked to as a leader and knowledgeable source of information among Exactech distributors. When Mr. O'Neill began experiencing problems with Dr. Moody's patients in Maine, he contacted Mr. Hebert, who informed him that around the 2008 time period "everyone was calling him;" meaning Mr. Hebert's high-volume surgeons were calling him reporting major problems with tibial loosenings due to the Finned Tibia Tray.

106. The following physicians are clients of Mr. Hebert who reported their patients experiencing abnormal tibial loosening problems with the Finned Tibia Tray to Mr. Hebert: Dr. Raymond Robinson, in Miami, FL; Dr. Ross Stone in Lake Worth, FL; Dr. Morton Bertram in Naples, FL; Dr. Nicholas Connors in Puenta Gorda, FL; Dr. Kirk Maes in Sebastian, FL; Dr. Robert Love in Palm Bay, FL and Dr. David Kreisberg in Melbourne Beach, FL.

107. Another surgeon who also reported significant tibial loosenings was Dr. Shekhar Desai based in Palm Bay, FL. In 2007, Dr. Desai was the third-largest volume surgeon using the Exactech Finned Tibia Tray, implanting 177 of the defective devices that year alone. In 2008, Dr. Desai became the largest volume surgeon, implanting 275 of the defective devices. When Dr. Desai reported that he was seeing patients with early-onset tibial loosenings – within six to twelve months of implantation – Relator Manuel Fuentes worked as the Exactech surgeon liaison to help Dr. Desai reverse engineer a "quick-fix" to the material design flaws inherent in the Optetrak Finned Tibia Tray.

108. This "quick fix" involved using significantly more cement than the Exactech instructions called for to secure the Finned Tibia Tray by creating "wider wings" in the keel of the Finned Tibia Tray with cement. These wider cement wings created a circumferential cement mantle

around the keel and provided the necessary stability to sufficiently anchor the Finned Tibia Tray. Eventually, Dr. Desai refused to use the defective Finned Tibia Tray despite Exactech's attempts to provide a "quick-fix." Because of his large patient volume and status as a preferred surgeon, Dr. Desai was provided the trapezoid tray, the much-larger tray that should have been used only for Revision TKR surgeries. Using the Revision TKR components for Primary TKR procedures meant more bone had to be removed from patients than was necessary, patients endured more significant recoveries and would never have the range of motion and mobility an actual Primary TKR device would have provided.

109. Dr. Shekhar Desai was also a well-paid Exactech consultant, which was at least one purpose of his continued loyalty to the Exactech brand – despite knowledge Exactech's primary product was woefully defective. Although, Dr. Desai's tenure as an Exactech consultant came to an abrupt halt in 2014, when Dr. Desai pleaded guilty to one count of conspiracy to commit wire fraud resulting from a different consulting agreement with DePuy Orthopaedics, Inc. This felony conviction stemmed from Dr. Desai's submitting billings for consulting services for which he did not perform.[31]

110. During the 2007-2008 time period, Kevin Bouley, an Exactech distributor based in the Boston, Massachusetts metro area informed Tim O'Neill that one of his orthopedic surgeon customers – Dr. Chris Hutchins, based in New Haven, Connecticut – also had 35 patients implanted with the Optetrak Finned Tibia Tray who experienced tibial loosenings, indicative of a

[31] USA v. Shekhar Desai Cr. 10-143 (D. N.J)(In his plea hearing, Dr. Deasi admitted that in or about September 2003, he entered into a consulting agreement with DePuy Orthopaedics, Inc, a subsidiary of Johnson & Johnson. Pursuant to that consulting agreement, Desai was to be paid for performing certain consulting services, including training sessions and operating room sessions. However, Desai admitted that from July 2004 through November 2005, he submitted invoices and requested payments from the J & J subsidiary for consulting services he never performed. Through his plea, Desai admitted that he received more than $70,000 and up to $120,000 in payments to which he was not entitled.) Press release available: https://www.justice.gov/sites/default/files/usao-nj/legacy/2014/09/02/desa0305rel.pdf

device failure, and required revision surgeries. When Mr. Bouley reported this to Exactech, the Company's leadership told him (as it told all others) that he was the only distributor with a physician experiencing tibial loosenings associated with the Finned Tibia Tray Optetrak TKR.

111. Relators also have knowledge that Dave Vandermosen, a former Exactech distributor in the Georgia territory, had relationships with several surgeons whose patients experienced tibial loosenings associated with the Finned Tibia Tray. These surgeons included Dr. Scott Gillogly in Atlanta, GA, Dr. Freddy Achecar in Douglasville, GA, Dr. David Covall in Cumming, GA, Dr. Jon Minter in Alpharetta, GA and Dr. John Doris in Athens, GA. Exactech repeated the standard line to all of them: that they were the only surgeons whose patients were experiencing the device failures.

112. Relator Fuentes knows of numerous surgeons who were Exactech customers in the 2007-2008 timeframe and experienced tibial loosenings. Further, Relator Fuentes is aware that many of these surgeons – typically high volume surgeons – were also engaged, around the same time, to be Exactech consultants. As alleged herein, Exactech provided these surgeons with consulting agreements to retain their business and secure their silence after their patients suffered a failed knee replacement requiring a revision surgery. Whether the consulting agreements were offered as a tacit agreement to buy silence or simply to distract the surgeons and gain their loyalty, the express purpose of the payments from Exactech's point of view was to diffuse the disastrous problem of the Finned Tibia Tray failing at outlier rates and keep the surgeons as loyal customers.

113. Below are surgeons that witnessed unusually high tibial loosenings resulting from device failures with the Finned Tibia Tray Optetrak TKR and are currently or were previously Exactech consultants:

Surgeon	**2007 Volume of Finned Tibia Tray Optetrak TKR**	**2008 Volume of Finned Tibia Tray Optetrak TKR**	**Location**
Dr. Raymond Robinson	207	123	Miami, FL
Dr. William Balcom	149	239	Worcester, MA
Dr. Phillip Lewandowski	147	162	Akron, OH
Dr. Scott Dunitz	143	172	Tulsa, OK
Dr. Morton Bertram	93	201	Naples, FL
Dr. Wayne Moody	129	149	Auburn, ME
Dr. David Covall	121	173	Cumming, GA
Dr. Mark Fahey	54	65	Tallahassee, FL
Dr. William Bose	52	84	Mobile, AL
Dr. Ajoy Sinha	57	60	Flushing, NY
Dr. Jay Mabrey	43	72	Dallas, Texas
Dr. Daniel Gallagher	41	59	Marrero, LA
Dr. Richard Boiardo	29	76	Elizabeth, N.J.
Dr. Stephen Davenport		53	Oklahoma City, OK
Dr. James Slater	24	49	Tulsa, OK
Dr. John Aldridge	18	41	Newport News, VA
Dr. James Bates	9	41	San Diego, CA

B. Exactech's Investigation of the Tibial Loosening Issues

114. Exactech engaged Dr. Ivan Gradisar to perform an audit of patient outcomes and develop a better understanding of the severity of the tibial loosening problem. As noted above, Dr. Gradisar's audit is attached as Exhibit A. This audit included a comprehensive review of patients from the Summa Health System Hospital in Akron, Ohio who received a revision knee replacement surgery during a seventeen-month period between January 1, 2004 and May 5, 2005 and a fifteen-month period between January 1, 2007 to April 1, 2008.

115. Dr. Gradisar was selected to perform this audit because he was one of the primary designers of the Optetrak TKR, and therefore received significant income through royalties on the sale of the Optetrak TKR and was viewed as a "friend of the company." Based on Dr. Gradisar's mutually aligned interest, Exactech believed Dr. Gradisar could be trusted to discretely investigate the tibial loosening issue and protect the company no matter what the results of the audit.

116. With this aim, Dr. Gradisar conducted an audit that was designed to produce a vague acknowledgement of the problems but not memorialize the extent of the known device failures. Dr. Gradisar accomplished this through a manipulative sample selection designed to skew the results. First, Dr. Gradisar reviewed patients from the Summa Health System that had received a revision Total Knee Arthroplasty surgery in which an Exactech component was involved as the Primary or Revision device from January 1, 2007 to March 31, 2008. This sample selection is manipulative because it includes surgeries in which a non-Exactech Primary TKR was then revised with an Exactech revision device. These surgeries have no bearing on assessing Primary Exactech Optetrak TKR device failures but including them in the audit does expand the sample size to reduce the percentage of failed Exactech Primary Optetrak TKR devices. Dr. Gradisar's

audit excluded specific patients from being reported as "Loose Exactech Tibial Trays" yet provided enough information that upon review that Relator Dr. Manuel Fuentes immediately recognized certain patients' revision surgeries were due to a loose Exactech tibial tray yet were not reported as such. Furthermore, several patients had both knees replaced with Exactech Optetrak TKR devices and both knees failed due to tibia loosenings – however, Dr. Gradisar only reported these patients as one loosening or did not categorize these failures as due to tibial loosening.

117. Despite the manipulations of the audit, of the 47 patients who received a TKR revision surgery between January 1, 2007 and March 31, 2008, Dr. Gradisar opined that 12 patients required revisions due to loose Exactech Finned Tibial Trays. Dr. Gradisar also categorized 10 of the 47 revisions as "Infected Requiring Revision." Relator Dr. Manny Fuentes notes this was a manipulative presentation of data because often knee replacements become infected due to loose components, most often a tibial tray loosening. Another four revisions of Exactech Finned Tibial Trays were attributed to a "broken tibial spine;" also a secondary condition usually caused by loose tibial tray. Further, Dr. Gradisar only categorized 33 of the 47 charts he reviewed, leaving many questions about the validity of his investigation. Nevertheless, a review of his patient summaries shows, in his self-selected sample, at least 24 Exactech Finned Tibia Trays failed, requiring a revision, due to tibial loosenings or tibial loosening related problems.

118. Many of Dr. Gradisar's remarks demonstrate the severity of the tibial loosening problem. One example, for Patient M.T., provides "11/22/06 [the date of the primary TKR surgery] OPTETRAK, RIGHT/LEFT PS CEMENTED…1/5/07 [date of revision surgery] – PL [Surgeon Phillip Lewandowski] REVISED BOTH TIBIAS…CCK [Constrained Congular Knee] CEMENT/BONE LOOSENING…BOTH IN VARUS. This notation means that Patient M.T.

received a double Optetrak TKR and within approximately 13 months the tibia portion of both knees had loosened to the point that the tibia tray stem was "in varus" - meaning at a crooked angle and not aligned with the tibia. This tibial loosening required Exactech consultant surgeon Phillip Lewandowski to revise both of Patient M.T.'s knees to a Constrained Congular Knee which is the most restrictive and thickest anchoring knee replacement device and requires an extensive amount of bone to be removed to secure the tibial anchoring device. However, patient M.T. was not classified as one of the "tibial loosening" patients in Dr. Gradisar's results. Relator Dr. Manuel Fuentes reviewed this description of Patient M.T.'s chart and believes Patient M.T.'s double knee revision within 13 months of primary surgery was clearly related to tibial loosenings and would have been reported as such in an objective audit.

119. Dr. Gradisar also provided a description of his audit, methods and his opinion of the causes of the tibial loosening issues. Dr. Gradisar begins "I have taken the list of all knee revisions at Summa done between 7/1/07 and 4/1/08 supplied by Mosher Medical [the Exactech distributor in the Akron, Ohio area] and reviewed the office charts looking for information regarding a possible tibia loosening issue." Gradisar continues: "I believe the issue has multiple causes and the order of significance may be different for each surgeon or even each patient." Dr. Gradisar then lists three cosmetic causes of the tibial loosening issue, the first of which becomes Exactech's primary excuse for the tibial loosening problem: problems with the surgeon's cement technique. The second and third causes are equally cosmetic and innocuous: 2. "never fail in varus particularly on the tibia" and 3. "avoid doing the morbidly obese patients." However, the fourth listed cause for the tibial loosening problem is "some implants may have a greater margin of error than others…"

120. Dr. Gradisar then describes basic orthopedic surgery protocol as "certain precautions that tilt the odds [against tibial loosening and device failure] favorably." Yet, in an apparent recommendation to do more than follow basic orthopedic standards to "tilt the odds of device failure favorably," Dr. Gradisar opines: "It may be possible to design a stem that is more forgiving, avoid features that lead to canal pressurization but develop a secure initial mechanical fit." In other words, the design of the Finned Tibia Tray "may be" flawed.

121. Despite the lack of objective data, the couched language, and the seemingly deliberate short-comings of Dr. Gradisar's patient audit, his report clearly provided Exactech with more than enough information to recognize that the Optetrak Finned Tibia Tray was failing at alarming rates well outside the industry norm. After receiving the results of the first patient audit, Relator Fuentes believes Exactech informed Dr. Gradisar that a previously planned further investigation would not be necessary, and cancelled the planned second set of patient reviews.

C. Exactech Misled the FDA by Failing to Submit Adverse Event Reports Based on Information in Dr. Gradisar's Audit

122. Dr. Gradisar's report, received by Exactech on or around April 1, 2008 also provides more than enough information to trigger Exactech's obligation to submit a report to the FDA regarding the identified revision surgeries because Exactech became aware of information, from a knowledgeable and focused source, that reasonably suggests that the Optetrak TKR and specifically the Finned Tibia Tray "may have caused or contributed to a serious injury" and that the Finned Tibia Tray has "malfunctioned and this device or a similar device would be likely to cause or contribute to a serious injury, if the malfunction were to recur." *See 21 U.S.C. § 360i; 21 C.F.R. §803.50.* This knowledge mandated Exactech submit not only the delineated information in FDA Form 3500A but also "any information in [Exactech's] possession" – clearly

encompassing Dr. Gradisar's audit and report in its entirety. 21 C.F.R. §803.50; 21 C.F.R. §803.52. Instead, they sequestered Dr. Gradisar's findings and cancelled the rest of the audit.

123. Moreover, by highlighting the significant device failures and by recommending as a solution that Exactech "design a stem that is more forgiving," Dr. Gradisar's report informs Exactech that remedial action is necessary to "prevent an unreasonable risk of substantial harm to the public health." Accordingly, Exactech was required to submit a report to the FDA within 5 days of receiving this information. *See* 21 C.F.R. §803.53. While they began working on a new design, Exactech never submitted the report to the FDA and continued to sell the Optetrak TKR.

124. In violation of the above-referenced FDA reporting regulations, specifically 21 C.F.R. §803.50; 21 C.F.R. §803.52, 21 C.F.R. §803.53, Exactech did not report any of the tibial loosenings or revision surgeries identified in Dr. Gradisar's audit.

125. However, Exactech did report 18 separate Adverse Events related to the Optetrak TKR system in 2008 to the FDA. Due to information provided by Dr. Moody and his distributor in Maine, Timothy O'Neill; Dr. Hutchins and his distributor Kevin Behlay and Dr. Gradisar's audit – all in the same late 2007-early 2008 time period – Relators have knowledge of roughly 100 revision surgeries directly resulting from Finned Tibia Tray loosenings. Considering over 100 revisions from just three orthopedic practices and not including the deluge of revisions in the highest volume territory in Florida (where revisions were known to be rampant), this number is grossly misleading. Therefore, Exactech's reporting of only 18 adverse events in 2008 was a knowing violation of the reporting requirements and materially misled the FDA.

126. It was not merely the lack of adverse event reports submitted by Exactech that constituted an intentional deception of the FDA, but also the materially false statements, half-truths and

misleading information contained within the reports that were submitted. Each of the 18 reports submitted in 2008 were materially false and misleading by both affirmative misrepresentation and by omission. For example, Report Number 1038671-2008-00035, submitted to the FDA on August 15, 2008 was the first report filed by Exactech after receipt of Dr. Gradisar's April 1, 2008 audit. This Report regards an "Optetrak Cruciate Retaining Tibial Insert" and the event description provides "A total knee arthroplasty was revised approximately one month post operatively, due to a report of wear." In this report Exactech makes the affirmative false statement that the report is not a Product Problem Report.

127. The next adverse event report submitted by Exactech related to the Optetrak system was submitted to the FDA on November 14, 2008 and provided it regards a "Cemented Finned Tibial Tray" – precisely the device that at the time was prompting repeated complaints by multiple surgeons and an internal audit by Exactech that revealed unusually high failure rates and an expert opinion that that the design was likely flawed. The event description provides "Revision of tka due to tibial loosening" – precisely the issue that Exactech knew was causing hundreds of other preventable revision surgeries. Yet, Exactech falsely represented to the FDA that the Report was only an Adverse Event Report, affirmatively and falsely stating it was not a Product Problem Report.[32] Exactech also did not provide an answer to the question "Was Device Evaluated by Manufacturer?"[33] The short answer to that question was: Yes. The complete answer was: yes and the evaluation demonstrated an unusually high failure rate suggestive of a design flaw. Exactech never filed a supplementary report nor provided an

[32] MAUDE Adverse Event Report: EXACTECH, INC. OPTETRACK CEMENTED FINNED TIBIAL TRAY. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=1240807&pc=HSH (last visited January 23, 2018)

[33] *Id.*

answer to this or the other unanswered questions in this initial report, in violation of 21 CFR 803.50(b)(3).

128. Similarly, Exactech submitted another Adverse Event Report regarding the Optetrak Cemented Finned Tibial Tray on November 21, 2008, and provided the following event description as if it were an anomaly even though it was characteristic of hundreds of other tibial loosenings: "A total knee arthroplasty (tka) was revised approx. 14 months post operatively, due to loosening."[34] Again, in this Adverse Event Report and all other Reports submitted in the same 2007-2008 timeframe, Exactech made material false statements that the adverse events were not related to a Product Problem and pervasively omitted any information that would alert the FDA that Exactech had conducted an internal investigation which resulted in Exactech recognizing that the Finned Tibia Tray had material design flaws and failed at an alarmingly high rate. Tellingly, none of the Adverse Event Reports mention anything about the surgeon's "cement technique" – which was the pretextual explanation Exactech provided to complaining surgeons.

D. Exactech's Identified Causes of Tibial Loosenings

129. As part of the internal investigation into the reports of tibial loosenings and mounting revision surgeries, Exactech engineers examined the suspected causes of the tibial loosening. Relator Manuel Fuentes was actively involved in this investigation in which several design engineering flaws were identified as potential causes of the tibial loosening problem.

130. First, Exactech discovered specific flaws in its own engineering process related to the sizer used for the Exactech Finned Tibia Tray which likely contributed to the tibial loosening

[34] MAUDE Adverse Event Report: EXACTECH, INC. OPTETRAK CEMENTED FINNED TIBIAL TRAY. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=1242525&pc=HSH (last visited January 23, 2018).

problem. Early in the trial phase of the Optetrak system, the design team – including Raymond Cloutier and Albert Burnstein – realized the Optetrak knee was not able to extend fully. To remedy this problem, the design team instructed to cut more of the femur bone away to create more space to allow for the proper flexing of the joint. As the team sought to create a symmetrical fit into the gaps in the bone that are made to fit the implant, the sizer had to also be adjusted to size for this extra space. The way Exactech accounted for the extra space required for full movement was to create what Relator Fuentes referred to as the "fudge factor," in which the sizer was intentionally made to be slightly inaccurate to "size down" the femoral component by a half size to create the extra room needed for full range of motion. With this adjustment, if a patient's femur was actually a size three, the sizer measured it as a size 2.5. In this common situation, when a patient measured at a half-size, Exactech recommended downsizing the smaller available size – which in this example would yield a patient measuring at a size two. This design flaw was not a problem until the Low Pressure Instrument 2 (LPI 2) came in mid-2006 to replace the earlier LPI 1 system that featured the fudge factor described above.

131. A relatively new engineer, Trevor Schluetter, was the primary designer of the LPI 2 sizer instrumentation. Mr. Schluetter was not with Exactech during the design phase of Optetrak and LPI 1. When Schluetter embarked to design the LPI 2, no one from Exactech informed him that the LPI 1 had this built-in hidden "fudge factor" and therefore Schluetter designed the LPI 2 to size accurately the femur without the "fudge factor." As a result, there was a large increase in size 3 femur 2 tibia (3F/2T) devices. The dimensions of the size two tibia corresponded to the size of the keel of the 2F/1T and 2F/2T tibial components, which was significantly smaller than the size three tibia keel.

132. With this smaller anchorage in the tibia being required to support the more substantial loads of a size three femur, the anchoring keel would wobble, creating a "see-saw" effect and eventually cause the tibia tray to become loose. While tibial loosening problems necessitated revision surgeries in all sizes of Optetrak knee replacement devices, this sizing problem led to widespread failure in size 3 femur, size 2 tibia devices. In fact, Relator Fuentes believes that the size 3F/2T tibia devices failed almost invariably. He reported this problem to his superiors who continued to sell the flawed device and did not report it to the authorities.

133. Another factor that compounded the problem of the failure of size 3F/2T devices was that the "punch" tool used to make the hole to seat the tibia tray in the bone only came in three sizes: size 1 and 2 tibias used the same size punch tool, size 3 and 4 used the same punch, and size 5 and size 6 shared the same punch. Therefore, when the sizing became distorted with the introduction of the LPI 2 instrumentation, an actual size 2 tibia could be sized as a size 3 and therefore the seating hole would be punched with the size 3 / size 4 punch – which created a hole actually large enough to seat a size 4 tibia – and thus created a hole far too large for the actual size 2 implant.

134. Yet another suspected cause of the Finned Tibia Tray tibial loosenings involved a change in the coating material used to cover the exterior of the Finned Tibia Tray. This cause was first presented by Tim O'Neill when he and Dr. Moody made their presentation to Exactech about the tibial loosening problem in 2007. Tim O'Neill as well as Exactech engineers upon their investigation noticed that the cemented portion of the early Exactech Finned Tibia Trays were covered with a gritty, porous coating – achieved through a "sand-blasting" process. However, the later tibia trays that were examined as part of tibial loosening investigation had a much shinier, polished surface finish. Exactech engineers and surgeons alike believed that this

polished surface finish did not hold to the surgical cement well and caused the tibial tray to become loose.

135. There were also other likely causes identified including that there was some type of manufacturing defect that caused the device's forgings to be a different shape as the actual implant. Due to this manufacturing defect, the tibial tray was unable to seat completely, causing it to more easily become loose.

136. Further, Dr. Gradisar, in his description and summary of his audit, opined that the blunt, rounded nose of the Finned Tibial Tray could increase fat "blow-back" as the tibial stem was inserted into the tibia. This slippery fat then covered the surface of the tibial stem and set up conditions for tibial loosening. This feature was ultimately changed when Exactech released its "Fit" Tray – the successor to the Finned Tray – as the Fit Tray featured a flat nose.

137. The Exactech engineering teams never reached a final consensus on the primary cause or hierarchy of causes of the tibial loosening problem. The general thought within Exactech was all of these design and potential manufacturing related problems created a "perfect storm" of issues – each contributing to the widespread tibial loosening issues. However, as the tibial loosening problem became undeniable, Exactech management ceased further investigation into the specific causes of the failures and proceeded to focus on cover-up efforts.

138. Several of these identified problem issues were specifically addressed and changed in the replacement Fit Tray – demonstrating that Exactech was aware of the problems but sought to correct them in secret. For instance, the implant's material was switched from a Titanium alloy to Cobalt–Chromium alloy, which was a stiffer material designed to be more adhesive with bone cement, the Fit Tray had a flat nose instead of a round nose like the Finned Tray to minimize fat

blow-back and the surface roughness in the Fit Tray was also altered to be a rougher, more gritty surface which was designed to enhance cement interdigitation in into the implant.

E. Exactech's Assessment of the Internal Investigation and Decision to Conceal the Device Malfunctions

139. In early 2008, based on the widespread reports of significant device failure, mounting revision surgeries and Dr. Gradisar's substantiation of these reports, it became apparent that there was a major problem with the Exactech Finned Tibia Tray. Exactech formed an investigatory committee to determine the causes and develop potential plans of action to address the widespread device failures. As a Senior Product Manager, Relator Manny Fuentes was an integral part of this investigatory committee. Other participants in these committee meetings included the leading engineers, product managers and executives within Exactech, including founder and then CEO Dr. Bill Petty and founder Dr. Gary Miller; Raymond Cloutier, Vice President of Research and Development; Alan Siedel, Chief Knee Engineer; Charley Rye, Director of Marketing; Xavier Sarabia, Vice President of Regulatory and Clinical and Jodie Phillips, Chief Financial Officer.

140. As the subject matter experts and Exactech Corporate Officers discussed the problems with the mounting reports of tibial loosenings associated with the Finned Tibia Tray, the conversation naturally focused on solving the problem and the manner in which Exactech would respond to its clear knowledge that thousands of patients had been implanted with a defective knee replacement device. Charley Rye, Director of Marketing, proposed the logical, natural and legal solution to issue a recall, pull the finned tray inventory from the market and replace it with the Revision TKR's Trap Tray. It was acknowledged that this plan of action would be financially detrimental to the company but it was Exactech's only option because the Finned Tibia Tray was the only primary TKR tibia tray Exactech produced.

141. CFO Jody Phillips then stood up and proclaimed that recalling the Finned Tray was not an option because it would be too financially detrimental to Exactech. Phillips explained that Exactech was "drowning in [Finned Tray] inventory" and the company could not afford to absorb the inventory cost. Further, Phillips stated that there was not enough Trap Tray inventory and the cost would be too high to ramp up production of enough Trap Trays to meet the demand needed to replace the Finned Tray. Therefore, Phillips' position was that if Exactech adhered to its legal and ethical obligations and disclosed the Finned Tray failures, the financial damage to the company would be too great and thus disclosure of any kind was not a viable financial option for the Company. Through Phillips' statements, the proposition of a company-wide cover up was on the table, emphatically presented by the CFO as the company's only option.

142. Xavier Sarabia, Exactech Vice President of Regulatory and Clinical, the Executive who was ostensibly charged with regulatory and legal compliance, did not object to Phillips' plan, which would obviously result in an organization-encompassing fraud. Instead of insisting that the company disclose the problems with the Finned Tibia Tray, Sarabia highlighted regulatory requirements that – if followed – could lead to suspicion and thus be problematic for the cover-up.

143. Specifically, Sarabia stated that the mounting revisions could become a problem because the FDA requires each revision to be reported, the device returned and paperwork submitted to the FDA. As detailed further herein, the regulatory requirements Sarabia was referring to are 21 U.S.C. 360i and 21 C.F.R. §803.5 and do, in fact, require medical device manufacturers to report individual adverse events, including knee replacement revision surgeries. C.F.R. §803.5.

144. Accordingly, Exactech knew it was required to disclose these precise problems to the FDA and was required to produce to the FDA the reports from its distributors of Finned Tibia

Tray failures, including the presentation made by Tim O'Neill and Dr. Moody and Dr. Gradisar's audit. After acknowledging these requirements, the top executives of Exactech decided to disregard these FDA reporting requirements, actively conceal this information, present affirmative false statements and misleading half-truths to the FDA, and continue to lie to surgeons in order to sell the defective Optetrak Finned Tibia Tray – causing false claims for payment to be made to government health care programs and untold harm to its patients, including U.S. military veterans and the elderly.

F. Exactech's Illegal Conduct Upon Deciding to Cover-up Wide-Scale Device Failure

145. With knowledge that the Finned Tibia Tray has material design flaws, Exactech embarked on a multi-faceted cover-up campaign that responded differently to individual surgeons based on the level of their influence with Exactech. If a surgeon was a high-volume established Exactech user that often had been an early adopter of Exactech products or involved in the design process of the Optetrak, then Exactech would placate that surgeon's concerns with the Finned Tibia Tray by providing that surgeon with the more expensive, more substantial and generally functional Trap Tray revision system. Examples of these "preferred surgeons" include Dr. Kyle C. Swanson of the Orthopedic and Fracture Clinic in Mankato, Minnesota. Dr. Kyle C. Swanson is the son of Dr. Gene Swanson – who was a primary consultant in the development of the Exactech Optetrak knee. Through this pedigree and Dr. Kyle C. Swanson's prolific use of Exactech Optetrak products – as the leading Optetrak user in 2007, implanting 220 devices and second most Optetrak user in 2008, implanting 256 devices – Dr. Kyle C. Swanson squarely fit within the "preferred surgeon" category.

146. Relator Manuel Fuentes has knowledge that Dr. Kyle C. Swanson was a consultant of Exactech's in the 2007-2008 timeframe. Furthermore, Dr. Kyle C. Swanson was and continues

to be a major consultant of Exactech's as data from the Open Payments system demonstrates: Dr. Kyle C. Swanson received consulting payments from Exactech of $31,360.63; $95,469.33; $136,120.88 and $136,897.45 in 2013; 2014; 2015 and 2016 respectively. Dr. Swanson's "preferred surgeon" status and, presumably, his knowledge of the problems of the Finned Tibia Tray led Dr. Kyle C. Swanson to request and be allowed to exclusively use the Exactech Trap Tray.

147. Similarly, Dr. Wayne Moody, upon presenting to Exactech the 51 of his patients requiring revisions due to problems with the Finned Tibia Tray, was also provided the Exactech Trap Tray for future patients, as well a consulting agreements calculated to distract and keep Dr. Moody silent about the problems with the Finned Tibia Tray and induce him to continue to use Exactech products.

148. However, not all surgeons were viewed by Exactech as "preferred surgeons" and many continued to be sold the Finned Tibia Tray long after Exactech knew of the material design flaws. These surgeons and the Exactech distributors that sold Exactech products to them were typically newer distributors and surgeons whom Exactech believed they could use to clear out their abundant inventory of Finned Tibia Trays.

G. Relators Wallace and Farley Are Provided the Finned Tibia Tray to Clear Exactech's Inventory

149. Relator Brooks Wallace became an Exactech sales representative in August 2011. Relator Farley became an Exactech sales representative in 2012. During their respective recruitments, Exactech pitched bot Relators Wallace and Farley on the Finned Tibia Tray as the primary Exactech TKR device and the flagship device of the Company. Exactech provided information on how effective, durable and superior the Finned Tibia Tray was compared to competitor products, even though they knew the Optetrak Finned Tibia Tray was defective and

failed at rates far outside industry norms. Specifically, Exactech sold Relator Farley and Wallace on the purported facts that the Optetrak Finned Tibia Tray was a revolutionarily successful implant and a significant improvement upon the previous generation Insall-Burstein Prothesis from which the Optetrak is based upon. Exactech claimed the range of motion, ease of surgical implantation and a completely fabricated survival rate of 98.6% at 8.5 years and 99% at 5 years made the Optetrak Finned Tibia Tray an industry leader.[35] Exactech knew these statements were false.

150. For these reasons, Relators Wallace and Farley became Exactech sales representatives and shortly thereafter Exactech distributors, managing a team of sales representatives, with the primary goal of selling Exactech's Optetrak with its Finned Tibia Tray to surgeons in their distributorship's Alabama and North Florida territory.

151. These representations were made to Relators Brooks Wallace and Robert Farley in 2011 and 2012 – years after Exactech had definitive knowledge that there were major design flaws with the Exactech Finned Tibia Tray that caused astronomical failure rates. Further, Exactech knew that specific sizes of the Finned Tibia Tray, specifically the size 3 femur, size 2 tibia, which was one of the most common sizes implanted, failed almost invariably. Such representations were also made after numerous surgeons refused to implant the Finned Tibia Tray because of product defects and Exactech provided consulting agreements to multiple surgeons to induce them to continue using Exactech products altogether. Plainly, Exactech had ample knowledge of the problems with the Finned Tibia Tray, but saw Relators Wallace and Farley as an unsuspecting mechanism to unload its stockpile of defective Finned Tibia Tray inventory.

[35] Optetrak- A Comprehensive Knee System; 712-01-21 Rev. D Optetrak Main Brochure 0410 (2010) available at: https://content.exac.com/wp-content/uploads/sites/3/2016/10/712-01-21_RevD_Optetrak_Main_Brochure.pdf

152. At no time during any discussions with Exactech about becoming distributors, the Exactech product line, or the Optetrak Finned Tibia Tray system did Exactech disclose to Relators Wallace and Farley that Exactech had received any information suggesting a potential problem with the Finned Tibia Tray. Specifically, there was no disclosure that three years earlier the company conducted a full investigation that demonstrated the device was defective and failed at alarming rates.

153. Upon becoming distributors, Relators Wallace and Farley's primary goal was to recruit orthopedic surgeons to use Exactech products – namely the company's flagship product, the Optetrak Finned Tibia Tray TKR. Relators Wallace and Farley sought out surgeons and (unknowingly) presented the same false efficacy and safety data that Exactech used to recruit Relators Farley and Wallace as distributors.

154. Upon starting the Exactech distributorship, Relator Brooks Wallace presented the Exactech Finned Tibia Tray to Dr. David Lemak – a well-respected orthopedic surgeon based in Birmingham, Alabama – who previously used Stryker products sold by Relator Wallace when Relator Wallace was a Stryker sales representative. Based on efficacy data and other sales materials supplied by Exactech falsely touting the superiority of the Optetrak and Finned Tibia Tray, Relator Wallace convinced Dr. Lemak to switch from using Stryker products to the Exactech Optetrak System and the Finned Tibia Tray for all of his patients' total knee replacements. This data was known by Exactech to be patently false and misleading in August 2011, at the time it was presented to Dr. Lemak.

155. With Dr. Lemak agreeing to exclusively use Exactech Optetrak TKR devices, Relators Farley and Wallace had their "keystone surgeon" and continued to expand their business to other surgeons in their territory. Thereafter, Relators Wallace and Farley marketed

and sold the Exactech Optetrak Finned Tibia Tray TKR device to numerous physicians in their Alabama and Northwest Florida territory including Dr. Joseph Sherrill in Birmingham, AL; Dr. John Young in Birmingham, AL; James Floyd, in Birmingham, AL; Dr. William Bose in Mobile, AL and Dr. Stephen Blackstock in Gadsden, AL.

156. From 2011 until 2014, Exactech supplied Relator Wallace with hundreds of Finned Tibia Trays. Each order and billing of an Optetrak Finned Tibia Tray TKR typically happened in the following manner: Relator Wallace would request a certain quantity of Optetrak Finned Tibia Tray TKR devices in varying sizes. Exactech would then ship these devices to Relator Wallace's office in Birmingham. When Dr. Lemak or another surgeon required a device for a patient scheduled for knee replacement, Relator Wallace attended the surgery, carried the full inventory of Optetrak devices, supplied the appropriate size TKR device, and filled out an Exactech form titled "Delivered Goods/Transfer of Inventory."

157. This form provided, among other information, the patient's name and identifying information, the hospital that would submit the cumulative billings to the patient's insurer – often a government healthcare program – and the Exactech products and corresponding model number and serial number.

158. By virtue of Relator Wallace's order forms (and his communications with Exactech), Exactech had knowledge that claims for payment were being submitted to government healthcare programs for defective medical devices. The order forms explicitly told Exactech that physicians in Alabama and North Florida, primarily Dr. David Lemak, were exclusively using the Finned Tibia Tray and implanting the defective devices in hundreds of patients – many insured by government healthcare programs. Exactech also knew that at least one of every three of those devices would fail and require a revision surgery – incurring more

cost to government healthcare programs but more revenue for Exactech. Exactech knew these claims were not reasonable or medically necessary. Exactech also knew that its own false representation and non-disclosure of the defective device facilitated submission and payment of these false claims.

159. Evidenced by Relator Wallace's order forms, Exactech had knowledge it was causing the submission of and conspiring to submit false claims to Medicare, Medicaid, and other programs and thus violating the FCA [and state FCAs]. "The False Claims Act subjects to civil liability any person who "knowingly presents, or causes to be presented, to ... the United States Government ... a false or fraudulent claim for payment or approval." *Britton ex rel. U.S. v. Lincare Inc.,* 634 Fed.Appx. 238, 240 (11th Cir. 2015) citing 31 U.S.C. 3729)(a)(1); *U.S. ex rel. Nevyas v. Allergan, Inc.,* 2015 WL 4064629, at *3 (E.D.Pa.,2015) citing *U.S. ex rel. Schmidt v. Zimmer, Inc.,* 386 F.3d 235 (3d Cir.2004)("Defendant who knowingly *cause* the submission of false claims may be liable under the FCA; the "knowledge and conduct of the defendant [is] what matter[s] and the outcome [does] not turn on whether the actual presenters were 'duped' or participated in the fraudulent scheme.")

160. Yet, Exactech continued to supply an unwitting Relator Wallace and his client Dr. Lemak and ultimately unknowing patients with defective medical devices. Exactech knew that as a new representative and a new surgeon to Exactech, Wallace and Dr. Lemak had no knowledge of the tibial loosening problems.

H. Relators Wallace and Farley Begin to Witness Tibial Loosenings and Requisite Revision Surgeries

161. In May 2014, after roughly two and a half years of exclusively using the Optetrak Finned Tibia Tray for his patient TKR operations, Dr. Lemak began to notice some surprising

and disturbing problems. The first time, he determined that a patient required a revision due to tibial loosening he believed it to be an outlier, because he was not accustomed to patients ever needing a revision so soon after their primary knee replacement. Similarly, Relator Wallace believed that this patient was an outlier because in his experience tibial loosening revisions were quite rare. In Relator Wallace's two years with Stryker, and selling roughly 1000 knee implants, Relator Wallace had never had a patient experience a tibial loosening.

162. Because it was Relator Wallace and Dr. Lemak's first time using the more substantial Optetrak Trap Tray Revision system, Relator Wallace requested that Exactech send a representative to oversee the surgery.

163. Exactech sent Anil Matura, a product engineer who worked in Exactech's corporate office in Gainesville, to assist and supervise this revision surgery. Upon arrival, Mr. Matura saw that the patient undergoing the revision received the Finned Tibia Tray as the Primary TKR device and asked Relator Wallace why Dr. Lemak was using the Finned Tray and not the newer Fit Tibia Tray. Relator Wallace explained that when he joined Exactech as a distributor he was provided the Finned Tibia Tray exclusively and that he, in turn, sold Dr. Lemak on the advantages of the Finned Tibia Tray. Relator Wallace further informed Mr. Matura that based on Exactech's promotion of the Finned Tibia Tray he had been exclusively using the Finned Tray for over two years – a fact which Exactech knew by their continued shipment of Finned Tray models.

164. Mr. Matura responded by obscurely stating that Exactech is in the process of switching all surgeons to the Fit Tray "because it gives more options."

165. At no point during this 2014 revision and attendant conversations did Mr. Matura inform Relator Wallace that the real reason Exactech was switching surgeons to the Fit Tray was

because the Finned Tray had major design flaws which led to widespread tibial loosenings and revision surgeries, nor did he inform him that Exactech conducted an internal investigation into the Finned Tibia Tray tibial loosenings six years earlier that confirmed those problems. Because of this lack of crucial information, Relator Wallace believed that the decision to switch to the newer Fit Tray was based merely on individual surgeons' preference and, at this time, never suspected there was anything wrong with the Finned Tray.

166. As 2014 progressed, however, more of Dr. Lemak's patients returned with pain, instability and other problems related to tibial loosening of their Optetrak Finned Tibia Trays. Two weeks after Anil Matura attended Dr. Lemak's first Finned Tibia Tray revision, Dr. Lemak contacted Relator Wallace to inform him two more of his patients needed revisions due to Finned Tray tibial loosening. A few weeks later, Dr. Lemak had to perform three more revision surgeries in one week due to Finned Tibia Tray loosenings. Each of these six patients' revision surgeries were required within roughly two years of their initial implant. As the revision surgeries piled up, Relator Wallace became increasingly concerned that there may be a real problem inherent to the Optetrak system or specifically the Finned Tibia Tray, which continued to fail.

I. Relator Wallace and Dr. Lemak Seek Answers From Exactech

167. Not only did Relator Wallace report each of these revision surgeries to Exactech and order the Trap Tray implants and other hardware required for each revision surgery, he actively sought answers as to why the Optetrak devices were failing.

168. By asking these questions, Relator Wallace and Relator Farley saw first-hand the progression of the Exactech "cover-up playbook." First, multiple Exactech representatives, including Exactech's Vice President of Sales for the Southeast Region Cary Christensen and

Exactech engineer Anil Matura, falsely denied that they knew of any other tibial loosenings or problems associated with the Optetrak system or Finned Tibia Tray.

169. Next, when Relator Wallace asked for a more substantive answer than a flat denial of ever previously encountering tibial loosenings, Exactech responded that the cause of the tibial loosening issue was Dr. Lemak's "cement technique"—while continuing to claim that no other surgeon had complained of tibial loosenings. This false answer was equally unsatisfying because not only had Dr. Lemak followed the cement instructions provided by Exactech, but at no point did Exactech offer to review Dr. Lemak's cement technique, provide any further instruction on the "proper cement technique" or otherwise provide any other detail about what specifically was purported to be wrong about Dr. Lemak's cement technique. Moreover, Dr. Lemak was and is an experienced orthopedic surgeon who never had any problems with his "cement technique" or experienced tibial loosenings and device failures in his patients

170. By December 2014, Dr. Lemak had performed seven or eight revisions due to Finned Tray tibial loosenings and was becoming increasingly frustrated with Exactech's response that he was the only surgeon who had reported problems and that the problems were caused by a flawed cement technique. Finally, Exactech corporate officers Bill Shopoff, Vice President of Sales, and Cary Christensen, V.P. of Sales for the Southeast region, traveled to Birmingham to meet with Relator Wallace and Dr. Lemak to discuss the tibial loosening problems in December 2014.

171. During this meeting, Dr. Lemak emphatically described the glaring extent of the tibial loosenings he was encountering in now-routine revision surgeries. Dr. Lemak and Relator Wallace both informed the Exactech Corporate Officers that during several of the revision

surgeries, they discovered that the tibial tray was so loose that Dr. Lemak could simply pull the metal hardware away from the patient's bone using his thumb and index finger. In light of this extreme degree of loosening, Dr. Lemak and Relator Wallace explained to Exactech's representatives that the problems are so pronounced and so unlike anything either of them had witnessed previously, that the loosening must be caused by an issue with the device and not Dr. Lemak's cement technique.

172. At one point, Dr. Lemak exclaimed that due to the extent of these problems, he did not believe it was possible that that he was the first surgeon to encounter tibial loosenings with the Finned Tibia Tray. To this direct confrontation, Bill Shopoff finally admitted that Exactech had, in fact, seen cases of tibial loosening with two other surgeons – one surgeon in Florida and one surgeon in Oklahoma. This admission only infuriated Dr. Lemak and Relator Wallace further because for the prior six months, and with revision surgeries mounting, Exactech claimed total ignorance and denied ever receiving reports of any tibial loosenings, and yet after all of those denials Bill Shopoff finally admitted that Exactech's party line was a lie.

173. After the December 2014 meeting, Exactech attempted to control the damage regarding the situation involving Dr. Lemak. During a follow-up conference call in January 2015, Joseph Pizzurro, Director of Marketing for the Exactech Knee Division sought to calm Dr. Lemak's concerns by telling him that Dr. Lemak was below the national average for revisions of Exactech Optetrak knee systems.

174. This unintended admission simply raised more red flags and caused further alarm for Relator Wallace and Dr. Lemak. Both Dr. Lemak and Relator Wallace have significant experience in orthopedics, yet had never encountered problems with an orthopedic implant as severe as with the Optetrak Finned Tibia Tray. Therefore, Exactech's disclosure that Dr. Lemak

was actually below the national average among surgeons for revisions only further highlighted that there were even more extensive tibial loosening problems elsewhere and that Exactech had been lying to Dr. Lemak and Relator Wallace throughout 2014. Dr. Lemak told Relator Wallace that he was infuriated with Exactech's unravelling deception and that his patients deserved better.

175. In follow-up communications with Joseph Pizzurro after the January 2015 conference call, Relator Wallace asked Mr. Pizzurro for further information about Optetrak revisions including what exactly was the national average for revisions of the Optetrak Finned Tibia Tray TKR. Relator Wallace also relayed Dr. Lemak's demand for data including the total number of Finned Tibia Tray revision surgeries that had been performed in the United States or he would no longer use Exactech products. Sensing that this request was far more information than Exactech could share, Pizzurro refused to comply, stating to Relator Wallace: "I won't give any information that would hurt the company."

J. Exactech Offers Dr. Lemak A Consulting Agreement

176. Faced with the possibility of losing Dr. Lemak as a customer or worse being exposed by Dr. Lemak, Exactech became desperate to contain him and distract him from his inquiry into the problems with the Finned Tibia Tray. Accordingly, Exactech turned to the next step in its cover-up playbook that had worked well in the past: offering money through the vehicle of a "consulting agreements." Shortly after the January 2015 conversations with Joseph Pizzurro, Cary Christensen, V.P. of Sales for the Southeast region, approached Dr. Lemak and explained that the then non-existent Exactech "Sports Medicine Division" was going to be expanding and that Exactech would appreciate Dr. Lemak becoming a consultant in the new Sports Medicine division. As a renowned sports medicine physician genuinely interested in

developing sports medicine products, Dr. Lemak accepted the offer and stayed on using Exactech products with the hope that he could get to the bottom of the problems with the Finned Tibia Tray and improve Exactech's products. He had no idea that the real purpose of the consulting agreement was an attempt to buy his loyalty and silence. Dr. Lemak's repeated requests for data regarding failure rates for the Finned Tibia Tray did not abate, however, to the dismay of Exactech and its executives.

177. Dr. Lemak's consulting agreement was rather minimal as compared to Exactech's other long-term consulting contracts because Dr. Lemak continued to be disturbed as his patients continued to return to him with loose tibia trays. Pursuant to the agreements, Dr. Lemak met twice with Exactech representatives and talked about Sports Medicine in general for a few hours and was paid several hundred dollars per hour for doing so. Dr. Lemak reported to Relator Wallace that the conversations were pointless and that he remained frustrated by Exactech's lack of response to his genuine concern about the tibial loosenings. Dr. Lemak's frustration with Exactech and the Finned Tibia Tray failures persisted and he continued to receive unsatisfactory answers from Exactech. Dr. Lemak's frustration is evidenced in an October 9, 2014 email exchange with a relatively low-level Exactech Guided Personalized Surgery sales representative, Erik Piorkowski.

178. Mr. Piorkowski reached out to Dr. Lemak, seeking his potential interest in continuing to use the Exactech GPS system and to schedule GPS surgeries, however he was met with Dr. Lemak's ire at the tibial loosenings who responded to Mr. Piorkowski's offer to conduct GPS cases by saying:

From: David Lemak <[redacted]
Date: October 9, 2014 at 6:30:37 PM EDT
To: "Piorkowski, Erik" <[redacted]>
Subject: Re: ExactechGPS

Tried to call brooks. Have had so many tibia component loosening (2 more last week and one today.) likely going to change prosthesis. Can't deal with revising all these patients in one to two years out.

Sent from my iPhone

179. Because Mr. Piorkowski was a new and relatively low level Exactech employee he was apparently unaware of Exactech's knowledge of the tibial loosening issue and its subsequent cover-up (which included never discussing tibial loosening problems over email), Piorowski forwarded Dr. Lemak's email to a group of Exactech corporate officers and senior employees and requested guidance on how to respond to Dr. Lemak's concerns. The group that Mr. Piorkowski forwarded this email to included: David Petty, CEO; Bill Petty, founder and Chairman of the Board; Gary Miller, Executive Vice President, Research and Development; Bill Shopoff, V.P. of Sales, Laurent Angibaud, Knee Principal Engineer and Cary Christensen; V.P. of Sales for Southeast region among others. Because he breached the company's unwritten protocol by taking Dr. Lemak's concerns of tibial loosening at face value and forwarding the email which could trace knowledge of the problem back to Exactech's corporate officers, Mr. Piorkowski was immediately ostracized within Exactech and bullied into leaving the company within five months of sending this email.

180. Relator Wallace and Dr. Lemak continued to see patients return with tibial loosening problems only one or two years after their primary TKR. Relator Wallace and Dr. Lemak relentlessly continued to raise the issue with Exactech, stating that there was a genuine problem with the Finned Tibia Tray. Exactech claimed to have developed a plan to address the tibial loosening problem. The integral portion of this plan, however, was to have Dr. Gary Miller and Laurent Angibaud come to Birmingham and attend a few of Dr. Lemak's surgeries, review

patient files and x-rays and supposedly "help [Dr. Lemak] to better understand the etiologies behind these [revision] cases."

181. Despite several emails from Dr. Miller, Laurent Angibaud and Relator Wallace attempting to set up this visit, it never materialized and Exactech never provided any meaningful explanation or education to Dr. Lemak on why his patients were plagued by tibial loosenings. Because Exactech had full knowledge of the inherent design problems with the Exactech Finned Tibia Tray and that dozens of surgeons previously experienced the same problems, any hypothetical consultation designed to educate Dr. Lemak would be ineffective at actually fixing the problems.

182. The combination of feigned surprise, intentional delay, and non-existent remedies coupled with the offer of sports medicine consulting agreements kept Dr. Lemak limping along with Exactech through October 2016. Each time a patient required a revision surgery, however, the situation became more tense.

K. Dr. Lemak Continues to Raise Concerns as More Patients Experience Pre-Mature Device Failure

183. Following the initial revision surgeries in 2014 through early 2015, Dr. Lemak's patients who received Finned Tibia Tray Primary TKRs in the 2011 to April 2014 timeframe continued to return to his clinic, and other Birmingham area orthopedists, with knee pain and instability indicative of tibial loosening problems. Each time a patient returned, Dr. Lemak accompanied by Relator Wallace was forced to perform a revision surgery to remove the Finned Tibia Tray and replace it with the Exactech Trap Tray revision system.

184. Relator Wallace estimates that Dr. Lemak performed 55 revision surgeries as of late 2017 – all on patients who were implanted with the Finned Tibia Tray. This figure does not

include patients who understandably went to another orthopedic surgeon when their knee replacement – promised to last them 30 years – began failing within less than five years.

185. As the revision surgeries continued week after week, Dr. Lemak grew more enraged and exasperated watching his patients subjected to preventable major knee surgery, because he unknowingly implanted what he was becoming convinced was a defective device. Dr. Lemak's anger and frustration became even more pronounced as he began to suspect that the company who sold the defective device knew it was defective long before Dr. Lemak agreed to use the product and lied to him to induce him to continue to use Exactech products. As the Exactech representative dealing directly with the surgeon on a day-to-day basis, Relator Wallace experienced the full force of Dr. Lemak's this anger and frustration.

186. The following situation was indicative of the severity of the loosening problems and Dr. Lemak's growing anger. Relator Wallace was attending one revision surgery at Grandview Hospital in Birmingham when Dr. Lemak was retrieving the loose Finned Tibia Tray from an unconscious patient's knee. Dr. Lemak was able to remove the Tray very easily by simply using his thumb and fore finger to grab the device. Even in other non-Exactech tibial loosening Revision surgeries, a surgeon would need forceps or some other surgical tool to remove a loose tibia tray. Holding the removed Tibia Tray in his hand, Dr. Lemak violently spiked the device onto the floor of the operating room in the direction of Relator Wallace. As Relator Wallace and the other surgery attendants ducked for cover, the metal device bounced off the floor several times. Throughout this surgery and particularly in this moment, Dr. Lemak was consistently cursing at Relator Wallace and "his company" (Exactech) for causing another one of his patients to undergo an unnecessary revision surgery.

187. Relator Wallace continued to inform Exactech about each Tibial Loosening and Dr. Lemak's growing anger and frustration. On May 23, 2016, at 10:31 PM, Relator Wallace forwarded Carey Christensen, Exactech's Vice President of Sales for the Southeast Region, a text message from Dr. Lemak which read:

> "Not sure about what brooks. It's nothing personal. I have 5 more revisions set up ASAP with the faulty tibial stem. I am about to report these failures to the board. It's above and beyond what's 'acceptable' and when I was 'told it was my technique' it was insulting and unjustified.
>
> These tibial stems are failing at a rate that is above "normal" rate. I have done so many more revisions of exactech tibial stems vs SnN [meaning Smith & Nephew] or Stryker over 10 years plus. I have repeatedly sent requests for explanation and review of cases. Basically laughed at. This is above and beyond 'normal' aseptic loosening.
>
> We have discussed over and over. I have been disregarded by Bill Petty and all others. Time for a change and I will support any patient who has an inquiry regarding their failure."

188. Upon receiving this direct reporting of a pervasive device failure, Exactech was then required to submit a report to the FDA within 5 days of receiving this information to "prevent an unreasonable risk of substantial harm to the public health" or at minimum submit an adverse event report regarding any of the five revision surgeries referenced by Dr. Lemak. *See 21 C.F.R. §803.53; 21 C.F.R. §803.50.* In violation of these regulations Exactech and with specific intent to conceal these problems from the FDA, Exactech buried Dr. Lemak's complaints and submitted nothing to the FDA.[36]

189. Instead, Carey Christensen responded by propounding Exactech's policy of dealing with physicians concerned about implanting a defective device by offering illegal remuneration in the form of consulting agreements, stating:

[36] MAUDE Database Search: Brand Name: Exactech; Report Date: 05/23/2016 to 07/23/2016. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/results.cfm

> "Suggest you call Dr. Miller. I had a long talk with Thien [Thien Doan, an employee that works with physicians in Exactech's Biologics Department] and he is ready to come to Birmingham and REALLY [emphasis in original] get David involved with sports side. Its time to get Dr. Miller to Birmingham. Can I forward that text to him?"

The plain meaning of Christensen's email is that it is time to "REALLY" pay Dr. Lemak to stop his complaints and buy his loyalty.

190. On October 10, 2016, Relator Wallace texted Carey Christensen requesting instructions how to fill out Dr. Lemak's timesheet for payment under the sports medicine consulting agreement. In the context of getting such instruction, and illustrating the connection between the tibial loosenings and the consulting payments, Relator Wallace also let Mr. Christensen know "He [Dr. Lemak] was complaining about tibial loosenings again this am. So wanted to stay on top of that for him."

191. However, on October 13, 2016, Dr. Lemak sent Relator Wallace the following email, with the Subject: Loosening Exactech total knees:

Brooks ,

I know we have assessed this subject many times in the past. I feel that the amount of loosening of the size 2 tibial components on the finned stems which I used for many years is unacceptable and above the normal amount of aseptic loosening. When I last addressed this I was told by Exactech that they haven't seen this as a problem. I fully disagree and continue to see more and more of these that require revisions.

I would like a full list of my revisions due to aseptic loosening. I again request an answer from exactech on the number of failures of this component. I think this needs to be reported.

Regards,

David

Sent from my iPhone

192. Five days later, on October 18, 2016, Dr. Lemak sent Relator Wallace the following email in the same chain:

Brooks,

I have had 3 more tibial stem loosening come into my clinic today. All similar 2-4 years out finned size 2. This is a serious problem that has negatively reflects on me as a surgeon. Makes my name " mud" in the community having to revise so many exactech arthroplasties. That being said , and with the lack of response or admission from exactech , I will be terminating my use of their components. I will of course need to revise the numerous cases that continue to arrive daily.

Regards,

David

193. Relator Wallace forwarded this chain of emails to Carey Christensen on October 18, 2016.

194. Carey Christensen, in turn, forwarded the email chain to the highest level Corporate Officers at Exactech.

195. Bill Petty, Chairman of the Board, Executive Vice President and Founder of Exactech, responded to Christensen and copied Gary Miller, CEO David Petty, CFO Jody Phillips, Director of Marketing for the Exactech Knee Division Joseph Pizzuro, Knee Principal Engineer Laurent Angibaud, and Vice President of Legal, Donna Edwards, on October 19, 2016:

From: Petty, Bill
Sent: Wednesday, October 19, 2016 8:52 AM
To: Christensen, Carey
Cc: Edwards, Donna; Petty, David; Phillips, Jody; Pizzurro, Joseph; Miller, Gary; Angibaud, Laurent
Subject: Re: Loosening exactech total knees

I guess my reply is that we moved him off the finned tray several years ago because he, like a few other surgeons, had a higher than expected loosening rate. We do not understand why he has had this loosening issue though I have discussed with him that a few other surgeons had it also. I believe that "admission" if we want to call it that and the move to the Fit tray was an appropriate response. I, for one, would be in favor of providing whatever replacement prosthesis is needed at no cost if that would make our response more real to Dr. Lemak.

Bill

Sent from my iPhone

196. This exchange verifies that Exactech and its leading corporate officers including the founder and Chairman of the Board, as late as October 2016, had been provided notice from an orthopedic surgeon who exclusively used their products that there was a significant problem with the Finned Tibia Tray – which caused dozens of his patients to undergo a revision surgery. At no point did Exactech report any of Dr. Lemak's concerns or patient revisions to FDA in violation of its' regulatory obligations and with specific intent to conceal these problems from the FDA. [37] *See 21 C.F.R. §803.53; 21 C.F.R. §803.50.* Although Exactech had planned to get Dr. Lemak "REALLY" involved in their "Sports Medicine" paid consulting program as an expert consultant – that plan was abandoned once Dr. Lemak informed Exactech that he would no longer use the company's components for his primary knee replacement surgeries.

L. Examples of Patients for Whom Exactech Caused False Claims to be Submitted

197. According to Medicare Claims Data, Dr. Lemak billed Medicare for 32 knee operations in 2012, the first year such data is available, under CPT code 27447, the coding for a

[37] MAUDE Database Search: Brand Name: Exactech; Report Date: 10/13/2016 to 12/31/2016. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/results.cfm

Primary Knee Reconstruction surgery.[38] Relator Brooks Wallace, as a Exactech distributor, was the sole supplier of Dr. Lemak's TKR devices and has knowledge that Dr. Lemak exclusively implanted the Finned Tibia Tray during 2012. Therefore, in 2012, Dr. Lemak implanted 32 Exactech devices into Medicare beneficiaries' knees known by the device manufacturer to be defective. In order to sell these 32 devices, Exactech materially falsified and withheld crucial information from Relator Wallace and Dr. Lemak and misled them both. By doing so, Exactech caused the submission of 32 false claims for devices that were not reasonable or medically necessary, in violation of 31 U.S.C. 3729.

198. Similarly, in 2013, Dr. Lemak billed Medicare for 36 knee operations under CPT code 27447. In order to sell these 36 devices, Exactech materially falsified and withheld crucial information from Relator Wallace and Dr. Lemak and misled them both. By doing so, Exactech caused the submission of 36 false claims for devices that were not reasonable or medically necessary, in violation of 31 U.S.C. 3729.

199. Patient RT is a Medicare patient, seen by Dr. Lemak, who was implanted with an Optetrak Finned Tibia Tray and who later required a Revision TKR surgery because the defective Exactech product resulted in tibial loosening. Patient RT received a Cemented TKA Revision surgery at Grandview Medical Center in Birmingham, Alabama on June 22, 2016. The wholesale cost of the Exactech parts implanted during the unnecessary Revision surgery totaled $5,095.

200. The following are examples of patients that received an Exactech Finned Tibia Tray Primary TKR under the care of Dr. James Floyd at Cooper Green Mercy Hospital in Birmingham, AL. At the time these patients received this implant, Exactech had known for over

[38] Medicare Physician and Other Supplier Data CY 2012

three years that the Finned Tibia Tray was defective and had a replacement device available. Though the inpatient surgery unit closed in December 2012 due to budgetary issues, Cooper Green Mercy Hospital has long been the sole hospital in the Birmingham Metro Area dedicated to indigent care – providing healthcare for a largely indigent and Medicaid eligible population.

A. Patient A.N, a Medicare eligible patient, received a Finned Tibia Tray Right TKR in January 2012. Relator Wallace sent Exactech a Delivered Goods form on January 21, 2012 informing Exactech that Patient A.N. received a medical device Exactech knew to be defective.

B. Patient K.P. received a Finned Tibia Tray Right TKR in January 2012. Relator Wallace sent Exactech a Delivered Goods form on January 5, 2012 informing Exactech that Patient K.P. received a medical device Exactech knew to be defective. The total wholesale cost of the device was $3,250.

C. Patient C.G. received a size 3F/2T (3 Femur, 2 Tibia) Finned Tibia Tray Left TKR in November 2011. Relator Wallace sent Exactech a Delivered Goods form on November 15, 2011 informing Exactech that Patient C.G. received a medical device Exactech knew to be defective and that Patient C.G. received the most problematic size of the device that Exactech knew failed nearly invariably. The total wholesale cost of the device was $3,200.

D. Patient G.W. received a size 3F/2T (3 Femur, 2 Tibia) Finned Tibia Tray Right TKR in January 2012. Relator Wallace sent Exactech a Delivered Goods form on January 17, 2012 informing Exactech that Patient G.W. received a medical device Exactech knew to be defective and that Patient G.W. received the most problematic size of the

device that Exactech knew failed nearly invariably. The total wholesale cost of the device was $3,250.

E. Patient H.D. received a Finned Tibia Tray Right TKR in February 2012. Relator Wallace sent Exactech a Delivered Goods form on February 21, 2012 informing Exactech that Patient H.D. received a medical device Exactech knew to be defective. The total wholesale cost of the device was $3,250.

M. Exactech's Claimed Optetrak Survival Rates Are Materially False and Misleading

201. Despite its' uncontroverted knowledge that the Exactech Finned Tibia Tray has major design flaws, incurring a revision rate far above any industry standard, Exactech continues to falsely represent that the Exactech Optetrak system has a survival rate of 98.6% at 8.5 years and a survival rate of 99% at five years.[39] This information is based on observational studies by two surgeons and referenced in the original Optetrak sales brochure – released in 2010 which features the Exactech Finned Tibia Tray on the cover. These two studies are referenced throughout all Exactech literature regarding the efficacy and survival rate of the Optetrak System.

202. The 98.6% at 8.5 years survival rate propounded by Exactech is based on a non-published, non-peer reviewed presentation made in 2004 by Dr. Ivan Gradisar – the same surgeon who performed the buried and intentionally misleading patient audit in April 2008 that demonstrated major problems with the Exactech Optetrak system.[40] Dr. Gradisar is also listed as one of six members of the Optetrak Design Team. This non-published, non-peer reviewed

[39] Optetrak- A Comprehensive Knee System; 712-01-21 Rev. D Optetrak Main Brochure 0410 (2010) available at: https://content.exac.com/wp-content/uploads/sites/3/2016/10/712-01-21_RevD_Optetrak_Main_Brochure.pdf

[40] Edwards J, Gradisar I Jr, Nadaud M, Kovacik M, Askey M. Eight and one-half year clinical experience with the Optetrak total knee prosthesis. Presented at the American Academy of Orthopaedic Surgeons. February 2004.

observation used a sample of 1575 knees replacements performed on 1,201 patients in Dr. Gradisar's own practice from June 1, 1994 until February 2004.

203. This observation claims only 13 of these 1575 knee required "re-operation" and only one re-operation was due to tibial loosening. However, in Dr. Gradisar's confidential audit of Exactech knee replacement patients in his practice four years later he reports that at least 24 revision surgeries were required in his clinic due to tibial loosenings. Exactech has hidden this 2008 report, not made any correction based on the updated data, and continues to knowingly and falsely propound the 2004 presentation as conclusive evidence that the Optetrak system has a 98.6% survival rate – based on only one tibial loosening revision.

204. The other study that Exactech relies upon for its claim that Exactech has survival rate of 99% at 5 years post-operatively was conducted by Dr. Raymond P. Robinson – another longtime Exactech consultant and surgeon.[41] Dr. Robinson's study is based on a sample of 66 knee replacements in 47 patients. All operations were performed by Dr. Robinson and he reported only one revision surgery, which was a patelloctomy due to a patella fracture.

205. However, and most importantly, Dr. Robinson's observation studied patients that exclusively received the Exactech Optetrak Trapezoid Tibial Tray, which was Exactech's larger, heavier tibial tray used as the revision surgery system and by all accounts was a functioning medical device, though not designed to be a Primary TKR device.[42] Therefore, no patient in this study, that Exactech has relied upon for years to proclaim a 99% survival rate for the entire Optetrak system, received the Finned Tibia Tray – which was used in the vast majority of Exactech Primary TKR operations and was the device known by Exactech to be defective and to

[41] Robinson RF. Five-year follow-up of primary Optetrak posterior stabilized total knee arthroplasties in osteoarthritis. *J Arthroplasty*. 2005 Oct;20(7):927-31.

[42] *Id. at 928 (*"The Optetrak Posterior Stabilized knee was used exclusively. A modular, titanium alloy metal-backed tibial component with trapezoidal cross-sectioned stem was used in all knees…included in this study.")

fail at an alarming rate. Moreover, because Dr. Gradisar's 2004 non-published, non-peer-reviewed presentation lacks significant medical data such as the type of Optetrak Tibia Tray used, it is unknown what percentage of patients in that report also received the Trapezoid Tray as opposed to the defective Finned Tray.

206. Exactech has conducted a systematic fraud upon federal health care programs, the FDA, surgeons who use its' products, investors, and ultimately patients who have been and continue to be implanted with the flawed Exactech Finned Tibia Tray by misleadingly and falsely conflating the Optetrak line of TKR devices as one device despite using materially different tibial components – one that is functional (the trapezoid tray) and one that is defective, much more commonly used, and destined to fail nearly a third of the time.

V. True Finned Tibia Tray Failure Rate

207. Because of this fraud, Exactech has intentionally made it difficult to discern an accurate survival rate, or more aptly termed, a failure rate of the Finned Tibia Tray. However, one study titled "Poor results of the Optetrak™ cemented posterior stabilized knee prosthesis after a mean 25-month follow-up: Analysis of 110 prostheses" (hereinafter "Thelu Article") was published in a peer-reviewed medical journal in 2012 and began to uncover the defective nature of the Finned Tray.[43] The Thelu Article, conducted by orthopedic experts and led C.E. Thelu in France, surveyed 110 Optetrak Finned Tray prosthesis and within a mean follow-up time of 25

[43] C.-E. Thelu, et al. "Poor results of the Optetrak™ cemented posterior stabilized knee prosthesis after a mean 25-month follow-up: Analysis of 110 prostheses" Orthopaedics & Traumatology: Surgery & Research (2012) **98**, 413—420

months. In that short time, 13 of the prostheses required revision.[44] Nine revisions were specifically for early loosening of the tibial component and at the end of the mean two year time period, another 10 patients remained with pain and "presented worrisome radiological and clinical signs indicating loosening or patellofemoral impingement." – meaning revision would be likely.[45] This study found the cumulated survival rate at 36 months for the Finned Tibia Tray Optetrak was 80.97 ± 9.1% and 76.74 ± 12% at 45 months.[46]

208. Despite pointing out the major flaws with the Finned Tibia Tray, primarily "early tibial loosening at the tibial tray – cement interface" and debunking Exactech's claimed reason for tibial loosening, "surgical technique [in context of cement] has not evolved compared to the original Insall implant (Ib II and its successor), which, at the same follow-up time, had not led to this type of problem," Thelu's article still missed the crucial point that has allowed Exactech's long-running fraud.

209. Thelu's article states: "Our revision rate with this implant is much higher than what has been reported by other teams with the *same prosthesis"* (emphasis added). The Thelu Article then cites to the 2005 Dr. Robinson study finding 99% survival rate of the trapezoid tibial component and a 2011 study by Dr. Robinson of only the all-polymer Optetrak tibial component (not the metal Finned tibial component) which found a 97% survival rate at a mean of 11.6 years.[47] Therefore, these compared revision rates pertain to different prosthesis as the studies

[44] *Id at 416.*
[45] *Id.*
[46] *Id.*
[47] *Id.*

assessed different tibial components with wildly different efficacy – one defective and two functional.

210. Relators have specific, independent and non-public knowledge of approximate failure rates of the Finned Tibia Tray in the United States. From August 2011 to April 2014, Dr. David Lemak performed roughly 215 Primary TKR operations using the Optetrak Finned Tray, a considerable statistical population size. Of those 215 Primary TKR operations, Dr. Lemak had to revise roughly 25%, performing 55 revisions as of July 2017 – all due to tibial loosenings. It is important to note that this number of 55 revision surgeries was and still is increasing consistently as more patients began to experience the often-delayed onset on problems caused by loose tibial components.

211. It is also important to note that this number of 55 revisions only accounts for patients that returned to Dr. Lemak for their revision surgery. Relators are aware of several patients that were understandably unsatisfied with Dr. Lemak and the Exactech TKR implant as it failed them within only a few years. Consequently, these patients, some known and surely some unknown, went to another orthopedic surgeon for the revision surgery.

212. Based on Dr. Lemak's data, the approximate failure rate of the Exactech Finned Tibia Tray TKR is at a minimum 25.5% over six years and estimated to be as high as 35% over that same period. This data comports with the ranges in the only other dataset that assessed the survival rate of the Finned Tray, the Thelu article, of 80.97 ± 9.1% at 36 months and 76.74 ± 12% at 45 months.

213. Further, Dr. Lemak himself noted the similarities in his patients' outcomes and the Thelu article, but over a shorter time frame. After, Carey Christensen tried to attack the viability of the Thelu article as last chance effort to keep Dr. Lemak using Exactech products, Dr. Lemak responded:

Dr petty can talk about how these authors publish poor studies. I haven't published anything however my clinical results mirror this study. Was told my dr petty that it was my " poor cementing technique ". Really ? I have just now seen my first smith and nephew gen 2 with aseptic loosening after ten years !!! So guess what my response is to them. These finned trays fail around two years. These are the facts.

I am happy to work with the sports med side and biologics. I will no longer support a company which has failed me and my patients. My reputation as a reconstruction surgeon has been tarnished. Let me know next step. Did my first four biomet joints today. Thanks for supporting my patients and allowing me to implant a prosthesis that has known failures of 25% at 25 months. Mimics my clinical results ..... my " cementing technique ".

214. Again, after being informed by a surgeon who implanted over 200 of Exactech's medical devices that it was a fact "[t]hese finned trays fail around two years" Exactech did not disclose any of this information to the FDA or anyone else, in violation of regulations specifically designed to prevent such occurrences. *See* 21 C.F.R. §803.50; 21 C.F.R. §803.52, 21 C.F.R. §803.53.

VI. Continued/Present Usage of Finned Tray

215. Although Exactech has stopped actively soliciting the Optetrak Finned Tray for implantation in the United States, the defective device is still on the market, available for sale to be implanted in patients in the U.S. (the defective Finned Tray is still widely sold to international

customers – primarily to physicians and patients in poor, third world countries). For instance, as late as September 2016, the Finned Tibia Component was on the product list for the V.A. and could have been purchased and implanted into a U.S. veteran's knee.

216. Furthermore, Relators have knowledge that some surgeons continue to implant the Finned Tibia Tray because Exactech has never disclosed the dangers of the device. Specifically, as of December 2016, a surgeon in Pittsburgh, Pennsylvania was implanting patients with the Finned Tibia Component knowingly supplied by Exactech. In its 2016 10-K report Exactech acknowledges: "[w]e also continue to support our classic Optetrak® knee system, a cruciate ligament sparing, posterior stabilized and a high flexion component, a unicondylar system and a constrained condylar design for revision surgery."[48]

VII. Exactech's Conduct Violated the False Claims Act

217. Exactech's conduct described herein violates in False Claims Act under established theories of law including the False Claims Act theories of fraudulent inducement, false certification and the "defective device" theory. *See United States v. Boston Scientific Corp.,* 2017 WL 3732099, at *6 (D.Minn., 2017). Furthermore, Exactech's pattern and practice of offering orthopedic surgeons illegal remuneration in the form of consulting agreements to continue to use Exactech products after the surgeons learned the Exactech Optetrak Finned Tibia Tray was defective is a clear violation of the Anti-Kickback Statute and thus the False Claims Act. 42 U.S.C. § 1320a-7b.

COUNT I

Federal False Claims Act
31 U.S.C. § 3729(a)(1)(A)

[48] Exactech 2016 10k available at https://content.exac.com/wp-content/uploads/sites/3/2017/05/EXAC-2016.12.31-10K-Final.pdf

218. The allegations in the preceding paragraphs are incorporated by reference.

219. Defendant knowingly presented or caused to be presented false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(A).

220. By virtue of the kickbacks (in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)), described above, Defendant caused to be presented false or fraudulent claims for and on behalf of federal health care program beneficiaries.

221. The United States, unaware of the falsity or fraudulent nature of the claims that Defendant caused, paid for claims that otherwise would not have been allowed. Defendant's representations were material to the government's decision to pay the device claims and attendant healthcare costs attributable to the defective nature of the device.

222. Because of these false or fraudulent claims, Defendant is liable to the United States for incurred damages resulting from such false claims, trebled, plus civil penalties for each violation of the Act.

223. As a result of Defendant's violations, the United States has suffered substantial damages in an amount to be determined at trial.

COUNT II

Federal False Claims Act:
31 U.S.C. 3729(a)(1)(B)

224. The allegations in the preceding paragraphs are incorporated by reference.

225. Defendant knowingly made, used, or caused to be made or used, a false record or statement material to a false or fraudulent claims for payment in violation of 31 U.S.C. § 3729 (a)(1)(B).

226. By virtue of the kickbacks (in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)), Defendant knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim for the improper payment or approval on behalf of federal health care program beneficiaries.

227. The United States, unaware of the falsity or fraudulent nature of the claims that Defendant caused, paid for claims that otherwise would not have been allowed. Defendant's representations were material to the government's decision to pay the false claims.

228. Because of these false or fraudulent claims, Defendant are jointly and severally liable to the United States for incurred damages resulting from such false claims, trebled, plus civil penalties for each violation of the Act.

229. As a result of Defendant's violations, the United States has suffered substantial damages in an amount to be determined at trial.

COUNT III

Federal False Claims Act:
31 U.S.C. § 3729(a)(1)(C)

230. The allegations in the preceding paragraphs are incorporated by reference.

231. Defendant knowingly conspired to present or cause to present false or fraudulent claims for payment or approval, conspired to make or use, a false record or statement material to a false or fraudulent claims and conspired to conceal or knowingly and improperly avoid or decrease obligations to pay or transmit money or property to the Government in violation of 31 U.S.C. § 3729(a)(1)(C).

232. By virtue of the kickbacks (in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)), described above, Defendant conspired to present and caused to be presented false or fraudulent claims for on behalf of federal health care program beneficiaries.

233. The United States, unaware of the falsity or fraudulent nature of the claims that Defendant caused, paid for claims that otherwise would not have been allowed. Defendant's representations were material to the government's decision to pay the device claims and attendant healthcare costs attributable to the defective nature of the device.

234. Because of these false or fraudulent claims, Defendant is liable to the United States for incurred damages resulting from such false claims, trebled, plus civil penalties for each violation of the Act.

235. As a result of Defendant's violations, the United States has suffered substantial damages in an amount to be determined at trial.

COUNT IV

Federal False Claims Act:
31 U.S.C. § 3729(a)(1)(G)

236. The allegations in the preceding paragraphs are incorporated by reference.

237. Defendant knowingly made, used, or caused to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, and/or knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money or property to the Government in violation of 31 U.S.C. § 3729 (a)(1)(G).

238. By virtue of kickbacks (in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)), misrepresentations and submissions of non-reimbursable claims on a corporate-wide basis described above, Defendant knowingly made, used, or caused to be made or used,

false records or statements material to an obligation to pay or transmit money or property to the Government, and/or knowingly concealed, avoided, or decreased an obligation to pay or transmit money or property to the Government in violation of 31 U.S.C. § 3729(a)(1)(G).

239. The United States, unaware of the falsity or fraudulent nature of the claims that Defendant caused, paid for claims that otherwise would not have been allowed. Defendant's representations were material to the government's decision to pay the claims.

240. Because of these false or fraudulent claims, Defendant is liable to the United States for incurred damages resulting from such false claims, trebled, plus civil penalties for each violation of the Act.

241. As a result of Defendant's violations, the United States has suffered substantial damages in an amount to be determined at trial.

COUNT V

Federal False Claims Based on Anti-Kickback Statute
31 U.S.C. § 3729(a)(1)(A); 42 U.S.C. § 1320a-7b(b)

242. The allegations in the preceding paragraphs are incorporated by reference.

243. Defendant knowingly presented or caused to be presented numerous false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729 (a)(1)(A).

244. By virtue of the kickbacks (in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)), misrepresentations and submissions of non-reimbursable claims on a corporate-wide basis described above, Defendant knowingly presented or caused to be presented false or fraudulent claims for the improper payment or approval on behalf of federal health care program beneficiaries.

245. The United States, unaware of the falsity or fraudulent nature of the claims that Defendant caused, paid for claims that otherwise would not have been allowed. Defendant's representations were material to the government's decision to pay the claims.

246. Because of these false or fraudulent claims, Defendant is liable to the United States for incurred damages resulting from such false claims, trebled, plus civil penalties for each violation of the Act.

247. As a result of Defendant's violations, the United States has suffered substantial damages in an amount to be determined at trial.

COUNT VI

California False Claims Act,
Cal. Gov't Code § 12650, et seq.

248. The allegations in the preceding paragraphs are incorporated by reference.

249. Relators also bring this action on behalf of the State of California, against Defendant under the California False Claims Act ("FCA"), Cal. Gov't Code § 12652(c).

250. Defendant, through their material non-disclosures and other wrongful acts and omissions set forth above, violated the provision of the California FCA, Cal. Gov't Code § 12651(a)(1), which creates liability for any person who "[k]nowingly presents or causes to be presented a false or fraudulent claim for payment or approval."

251. Defendant, through their material non-disclosures and other wrongful acts and omissions set forth above, violated the provision of the California FCA, Cal. Gov't Code § 12651(a)(2), which creates liability for any person who "[k]nowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim."

252. Defendant, through their material non-disclosures and other wrongful acts and omissions set forth above, violated the provision of the California FCA, Cal. Gov't Code § 12651(a)(7), which creates liability for any person who "[k]nowingly makes, uses, or causes to be made or used a false record or statement material to an obligation to pay or transmit money or property to the state or to any political subdivision, or knowingly conceals or knowingly and improperly avoids, or decreases an obligation to pay or transmit money or property to the state or to any political subdivision."

253. Pursuant to the California FCA, based on Defendant's material non-disclosures and other wrongful acts and omissions set forth above, Defendant is liable to the State of California for treble damages, civil penalties, and all other relief authorized by law. Cal. Gov't Code § 12651(a)(1).

254. As a result of Defendant's violations, the State of California has suffered damages in an amount to be determined at trial.

COUNT VII

Connecticut False Claims Act
CT. Gen Stat § 17b-301 et seq.

255. The allegations in the preceding paragraphs are incorporated by reference.

256. Relators also bring this action on behalf of the State of Connecticut, against Defendant under the State of Connecticut's False Claims Act ("FCA"), CT. Gen Stat § 17b-301b

257. Defendant, through material non-disclosures and other wrongful acts and omissions set forth above, violated the provision of the Connecticut FCA, CT. Gen Stat § 17b-301b(1), which creates liability for any person who "[k]nowingly presents or cause to be presented a false or fraudulent claim for payment or approval."

258. Defendant, through material non-disclosures and other wrongful acts and omissions set forth above, violated the provision of the Connecticut FCA, CT. Gen Stat § 17b-301b(2), which creates liability for any person who [k]nowingly make[s], use[s] or cause[s] to be made or used, a false record or statement material to a false or fraudulent claim under a medical assistance program administered by the Department of Social Services.

259. Defendant, through material non-disclosures and other wrongful acts and omissions set forth above, violated the provision of the Connecticut FCA, CT. Gen Stat § 17b-301b(3), which creates liability for any person who conspires to violate the Connecticut FCA.

260. Pursuant to the Connecticut FCA, based on Defendant's material non-disclosures and other wrongful acts and omissions set forth above, Defendant is liable to the State of Connecticut for treble damages, civil penalties, and all other relief authorized by law. CT. Gen Stat § 17b-301b(8)(b)

261. As a result of Defendant's violations, the State of Connecticut has suffered damages in an amount to be determined at trial.

COUNT VIII

Colorado Medicaid False Claims Act
CO ST § 25.5-4-304, *et seq.*

262. The allegations in the preceding paragraphs are incorporated by reference.

263. Relators also bring this action on behalf of the State of Colorado, against Defendant under the State of Colorado's Medicaid False Claims Act, CO ST. § 25.5-4-305.

264. Defendant, through material non-disclosures and other wrongful acts and omissions set forth above, violated the provision of the Colorado Medicaid False Claims Act, CO

ST. § 25.5-4-305(1)(a) which creates liability for any person who "[k]nowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval."

265. Defendant, through material non-disclosures and other wrongful acts and omissions set forth above, violated the provision of the Colorado Medicaid False Claims Act, CO ST. § 25.5-4-305(1)(b) which creates liability for any person who "[k]knowingly makes uses, or causes to be made or used a false record or statement material to a false or fraudulent claim."

266. Defendant, through material non-disclosures and other wrongful acts and omissions set forth above, violated the provision of the Colorado Medicaid False Claims Act, CO ST. § 25.5-4-305(1)(g) which creates liability for any person who "[c]onspires to commit a violation of the Colorado Medicaid False Claims Act."

267. Pursuant to the Colorado Medicaid False Claims Act, based on Defendant's material non-disclosures and other wrongful acts and omissions set forth above, Defendant is liable to the State of Colorado for treble damages, civil penalties, and all other relief authorized by law. CO ST. § 25.5-4-305(1).

268. As a result of Defendant's violations, the State of Colorado has suffered damages in an amount to be determined at trial.

COUNT IX

District of Columbia False Claims Act
D.C. Code § 2-381.01, *et seq.*

269. The allegations in the preceding paragraphs are incorporated by reference.

270. Relators also bring this action on behalf of the District of Columbia, against Defendant under the District of Columbia's False Claims Act (D.C. FCA). D.C. Code § 2-381.01, *et seq.*

271. Defendant, through material non-disclosures and other wrongful acts and omissions set forth above, violated the provision of the D.C. FCA, D.C. Code § 2-381.02(a)(1) which creates liability for any person who "[k]nowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval."

272. Defendant, through material non-disclosures and other wrongful acts and omissions set forth above, violated the provision of the D.C. FCA, D.C. Code § 2-381.02(a)(2) which creates liability for any person who "knowingly makes, uses or causes to be made or used a false record or statement material to a false or fraudulent claim."

273. Defendant, through material non-disclosures and other wrongful acts and omissions set forth above, violated the provision of the D.C. FCA, D.C. Code § 2-381.02(a)(7) which creates liability for any person who conspires to violate the D.C. FCA.

274. Pursuant to the D.C. FCA, based on Defendant's material non-disclosures and other wrongful acts and omissions set forth above, Defendant is liable to the District of Columbia for treble damages, civil penalties, and all other relief authorized by law. D.C. Code § 2-381.02(a)

275. As a result of Defendant's violations, the District of Columbia has suffered damages in an amount to be determined at trial.

COUNT X

Florida False Claims Act,
Fla. Stat. § 68.081, et seq.

276. The allegations in the preceding paragraphs are incorporated by reference.

277. Relators also bring this action on behalf of the State of Florida, against Defendant under the State of Florida's False Claims Act ("FCA"), Fla. Stat. § 68.083(2).

278. Defendant, through their material non-disclosures and other wrongful acts and omissions set forth above, violated the provision of the Florida FCA, Fla. Stat. § 68.082(2)(a), which creates liability for any person who "[k]nowingly presents or causes to be presented a false or fraudulent claim for payment or approval."

279. Defendant, through their material non-disclosures and other wrongful acts and omissions set forth above, violated the provision of the Florida FCA, Fla. Stat. § 68.082(2)(b), creates liability for any person who "[k]nowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim."

280. Defendant, through their material non-disclosures and other wrongful acts and omissions set forth above, violated the provision of the Florida FCA, Fla. Stat. § 68.082(2)(g), which creates liability for any person who "[k]nowingly makes, uses, or causes to be made or used a false record or statement material to an obligation to pay or transmit money or property to the state, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state."

281. Pursuant to the Florida FCA, based on Defendant's material non-disclosures and other wrongful acts and omissions set forth above, Defendant is liable to the State of Florida for treble damages, civil penalties, and all other relief authorized by law. Fla. Stat. § 68.082(2).

282. As a result of Defendant's violations, the State of Florida has suffered damages in an amount to be determined at trial.

COUNT XI

Georgia False Medicaid Claims Act,

O.C.G.A. § 49-4-168, et seq.

283. The allegations in the preceding paragraphs are incorporated by reference.

284. Relators also bring this action in the name of the State of Georgia, against Defendant pursuant to the State of Georgia False Medicaid Claims Act ("FMCA"), O.C.G.A. § 49-4-168 *et seq.*

285. Defendant, through their material non-disclosures and other wrongful acts and omissions set forth above, violated the provision of the Georgia FMCA, O.C.G.A. § 49-4-168.1(a)(1), which creates liability for any person who "[k]nowingly presents or causes to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval."

286. Defendant, through their material non-disclosures and other wrongful acts and omissions set forth above, violated the provision of the Georgia FMCA, O.C.G.A. § 49-4-168.1(a)(2), which creates liability for any person who "[k]nowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim."

287. Defendant, through their material non-disclosures and other wrongful acts and omissions set forth above, violated the provision of the Georgia FMCA, O.C.G.A. § 49-4-168.1(a)(7), which creates liability for any person who "[k]nowingly makes, uses, or causes to be made or used a false record or statement material to an obligation to pay or transmit property or money to the Georgia Medicaid program, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit property or money to the Georgia Medicaid program."

288. Pursuant to the Georgia FMCA, based on Defendant's material non-disclosures and other wrongful acts and omissions set forth above, Defendant is liable to the State of Georgia

for treble damages, civil penalties, and all other relief authorized by law. O.C.G.A. § 49-4-168.1(a).

289. As a result of Defendant's violations, the State of Georgia has suffered damages in an amount to be determined at trial.

COUNT XII

Hawaii False Claims Act
Haw. Rev. Stat. § 661-21

290. The allegations in the preceding paragraphs are incorporated by reference.

291. Relators also bring this action on behalf of the State of Hawaii, against Defendant under the Hawaii False Claims Act. Haw. Rev. Stat. § 661-21.

292. Defendant, through their material non-disclosures and other wrongful acts and omissions set forth above, violated the provision of the Hawaii FCA, Haw. Rev. Stat. § 661-21(a)(1) which creates liability for any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval."

293. Defendant, through their material non-disclosures and other wrongful acts and omissions set forth above, violated the provision of the Hawaii FCA, Haw. Rev. Stat. § 661-21(a)(1) which creates liability for any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval."

294. Defendant, through their material non-disclosures and other wrongful acts and omissions set forth above, violated the provision of the Hawaii FCA, Haw. Rev. Stat. § 661-21(a)(2) which creates liability for any person who "[k]knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim."

295. Defendant, through their material non-disclosures and other wrongful acts and omissions set forth above, violated the provision of the Hawaii FCA, Haw. Rev. Stat. § 661-21(a)(8) which creates liability for any person who "[k]nowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim."

296. Pursuant to the Hawaii FCA, based on Defendant's material non-disclosures and other wrongful acts and omissions set forth above, Defendant is liable to the State of Hawaii for treble damages, civil penalties, and all other relief authorized by law. Haw. Rev. Stat. § 661-21(a)(8)

297. As a result of Defendant's violations, the State of Hawaii has suffered damages in an amount to be determined at trial.

COUNT XIII

Illinois False Claims Act,
740 Ill. Comp. Stat. 175/1, et seq.

298. The allegations in the preceding paragraphs are incorporated by reference.

299. Relators also bring this action on behalf of the State of Illinois, against Defendant under the Illinois False Claims Act ("FCA"), 740 Ill. Comp. Stat. 175/4(b).

300. Defendant, through their material non-disclosures and other wrongful acts and omissions set forth above, violated the provision of the Illinois FCA, 740 Ill. Comp. Stat. 175/3(a)(1)(A), which creates liability for any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval."

301. Defendant, through their material non-disclosures and other wrongful acts and omissions set forth above, violated the provision of the Illinois FCA, 740 Ill. Comp. Stat.

175/3(a)(1)(B), which creates liability for any person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim."

302. Defendant, through their material non-disclosures and other wrongful acts and omissions set forth above, violated the provision of the Illinois FCA, 740 Ill. Comp. Stat. 175/3(a)(1)(G), which creates liability for any person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the State, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the State."

303. Pursuant to the Illinois FCA, based on Defendant's material non-disclosures and other wrongful acts and omissions set forth above, Defendant is liable to the State of Illinois for treble damages, civil penalties, and all other relief authorized by law. 740 Ill. Comp. Stat. 175/3(a).

304. As a result of Defendant's violations, the State of Illinois has suffered damages in an amount to be determined at trial.

COUNT XIV

Indiana Medicaid False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.7, et seq.

305. The allegations in the preceding paragraphs are incorporated by reference.

306. Relators also bring this action on behalf of the State of Indiana, against Defendant under the State of Indiana False Claims and Whistleblower Protection Act ("FCA"), Ind. Code § 5-11-5.7-4(a).

307. Defendant, through their material non-disclosures and other wrongful acts and omissions set forth above, violated the provision of the Indiana FCA, Ind. Code § 5-11-5.7-

2(a)(l), creates liability for any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval."

308. Defendant, through their material non-disclosures and other wrongful acts and omissions set forth above, violated the provision of the Indiana FCA, Ind. Code § 5-11-5.7-2(a)(2), creates liability for any person who "knowingly makes, uses, or causes to be made or used, a false record or statement that is material to a false or fraudulent claim."

309. Defendant, through their material non-disclosures and other wrongful acts and omissions set forth above, violated the provision of the Indiana FCA, Ind. Code § 5-11-5.7-2(a)(6)(A)-(B), which creates liability for any person who "(A) makes, uses, or causes to be made or used, a false record or statement concerning an obligation to pay or transmit money or property to the state; or (B) conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state."

310. Pursuant to the Indiana FCA, based on Defendant's material non-disclosures and other wrongful acts and omissions set forth above, Defendant is liable to the State of Indiana for treble damages, civil penalties, and all other relief authorized by law. Ind. Code § 5-11-5.5-2(b).

311. As a result of Defendant's violations, the State of Indiana has suffered damages in an amount to be determined at trial.

COUNT XV

Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:437.1, et seq.

312. The allegations in the preceding paragraphs are incorporated by reference.

313. Relators also bring this action on behalf of the State of Louisiana's medical assistance programs, against Defendant under the State of Louisiana Medical Assistance Programs Integrity Law ("FCA"), La. Rev. Stat. Ann. § 46:439.1.A.

314. Defendant, through their material non-disclosures and other wrongful acts and omissions set forth above, violated the provision of the Louisiana FCA, La. Rev. Stat. Ann. § 46:438.3.A, which states that "[n]o person shall knowingly present or cause to be presented a false or fraudulent claim."

315. Defendant, through their material non-disclosures and other wrongful acts and omissions set forth above, violated the provision of the Louisiana FCA, La. Rev. Stat. Ann. § 46:438.3.B, which states that "[n]o person shall knowingly engage in misrepresentation or make, use, or cause to be made or used, a false record or statement material to a false or fraudulent claim."

316. Defendant, through their material non-disclosures and other wrongful acts and omissions set forth above, violated the provision of the Louisiana FCA, La. Rev. Stat. Ann. § 46:438.3.C, which states that "[n]o person shall knowingly make, use, or cause to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the medical assistance programs, or to knowingly conceal, avoid, or decrease an obligation to pay or transmit money or property to the medical assistance programs."

317. Pursuant to the Louisiana FCA, based on Defendant's material non-disclosures and other wrongful acts and omissions set forth above, Defendant is liable to the State of Louisiana for treble damages, civil penalties, and all other relief authorized by law. La. Rev. Stat. Ann. § 46:438.6.

318. As a result of Defendant's violations, the State of Louisiana has suffered damages in an amount to be determined at trial.

COUNT XVI

Maryland False Health Claims Act,
Md. Code Ann. Health-Gen. § 2-601, *et seq.*

319. The allegations in the preceding paragraphs are incorporated by reference.

320. Relators also bring this action on behalf of the State of Maryland, against Defendant under the State of Maryland False Health Claims Act ("FCA"), Md. Code Ann. Health-Gen. § 2-604(a)(1).

321. Defendant, through their material non-disclosures and other wrongful acts and omissions set forth above, violated the provision of the Maryland FCA, Md. Code Ann. Health-Gen. § 2-602(a)(1), which states that a person may not "[k]nowingly present or cause to be presented a false or fraudulent claim for payment or approval."

322. Defendant, through their material non-disclosures and other wrongful acts and omissions set forth above, violated the provision of the Maryland FCA, Md. Code Ann. Health-Gen. § 2-602(a)(2), which states that a person may not "[k]nowingly make, use, or cause to be made or used a false record or statement material to a false or fraudulent claim."

323. Defendant, through their material non-disclosures and other wrongful acts and omissions set forth above, violated the provision of the Maryland FCA, Md. Code Ann. Health-Gen. § 2-602(a)(7), which states that a person may not "[k]nowingly make, use, or cause to be made or used, a false record or statement material to an obligation to pay or transmit money or other property to the State."

324. Defendant, through their material non-disclosures and other wrongful acts and omissions set forth above, violated the provision of the Maryland FCA, Md. Code Ann. Health-Gen. § 2-602(a)(8), which states that a person may not "[k]nowingly conceal, or knowingly and improperly avoid or decrease, an obligation to pay or transmit money or other property to the State."

325. Defendant, through their material non-disclosures and other wrongful acts and omissions set forth above, violated the provision of the Maryland FCA, Md. Code Ann. Health-Gen. § 2-602(a)(9), which states that a person may not "[k]nowingly make any other false or fraudulent claim against a State health plan or a State health program."

326. Pursuant to the Maryland FCA, based on Defendant's material non-disclosures and other wrongful acts and omissions set forth above, Defendant is liable to the State of Maryland for treble damages, civil penalties, and all other relief authorized by law. Md. Code Ann. Health-Gen. § 2-602(b).

327. As a result of Defendant's violations, the State of Maryland has suffered damages in an amount to be determined at trial.

COUNT XVII

The Commonwealth of Massachussetts False Claims Act, Mass. Ann. Laws Ch. 12 § 5A, *et seq.*

328. The allegations in the preceding paragraphs are incorporated by reference.

329. Relators also bring this action on behalf of the Commonwealth of Massachusetts, against Defendant under the Massachusetts False Claims Act ("FCA"), Mass. Ann. Laws ch. 12, § 5C(2).

330. Defendant, through their material non-disclosures and other wrongful acts and omissions set forth above, violated the provision of the Massachusetts FCA, Mass. Ann. Laws ch. 12, § 5B(1), which creates liability for any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval."

331. Defendant, through their material non-disclosures and other wrongful acts and omissions set forth above, violated the provision of the Massachusetts FCA, Mass. Ann. Laws ch. 12, § 5B(2), creates liability for any person who "knowingly makes, uses or causes to be made or used a false record or statement material to a false or fraudulent claim."

332. Defendant, through their material non-disclosures and other wrongful acts and omissions set forth above, violated the provision of the Massachusetts FCA, Mass. Ann. Laws ch. 12, § 5B(9), which creates liability for any person who "knowingly makes, uses or causes to be made or used a false record or statement material to an obligation to pay or to transmit money or property to the commonwealth or a political subdivision thereof, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the commonwealth or a political subdivision thereof."

333. Pursuant to the Massachusetts FCA, based on Defendant's material non-disclosures and other wrongful acts and omissions set forth above, Defendant is liable to the Commonwealth of Massachusetts for treble damages, civil penalties, and all other relief authorized by law. Mass. Ann. Laws ch. 12, § 5B(a).

334. As a result of Defendant's violations, the Commonwealth of Massachusetts has suffered damages in an amount to be determined at trial.

COUNT XVIII

Michigan Medicaid False Claims Act,

Mich. Comp. Laws Serv. § 400.601, *et seq.*

335. The allegations in the preceding paragraphs are incorporated by reference.

336. Relators also bring this action in the name of the State of Michigan, against Defendant under the State of Michigan Medicaid False Claims Act ("FCA"), Mich. Comp. Laws Serv. § 400.610a(l).

337. Defendant, through their material non-disclosures and other wrongful acts and omissions set forth above, violated the provision of the Michigan FCA, Mich. Comp. Laws Serv. § 400.607(1), which states that "[a] person shall not make or present or cause to be made or presented to an employee or officer of this state a claim under the social welfare act, 1939 PA 280, MCL 400.1 to 400.119b, upon or against the state, knowing the claim to be false."

338. Defendant, through their material non-disclosures and other wrongful acts and omissions set forth above, violated the provision of the Michigan FCA, Mich. Comp. Laws Serv. § 400.607(3), which states that "[a] person shall not knowingly make, use, or cause to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state pertaining to a claim presented under the social welfare act."

339. Pursuant to the Michigan FCA, based on Defendant's material non-disclosures and other wrongful acts and omissions set forth above, Defendant is liable to the State of Michigan for treble damages, civil penalties, and all other relief authorized by law. Mich. Comp. Laws. Serv. § 400.612.

340. As a result of Defendant's violations, the State of Michigan has suffered damages in an amount to be determined at trial.

COUNT XIX

New Hampshire False Claims Act

N.H. Rev. Stat. Ann. § 167:61-B, et seq.

341. The allegations in the preceding paragraphs are incorporated by reference.

342. Relators also bring this action on behalf of the State of New Hampshire, against Defendant under the State of New Hampshire False Claims Act ("FCA"), N.H. Rev. Stat. Ann. § 167:61-b, et seq.

343. Defendant, through their material non-disclosures and other wrongful acts and omissions set forth above, violated each of the following provisions of The New Hampshire FCA, N.H. Rev. Stat. Ann. § 167:61-b, which create liability for any person who:

> "(a) Knowingly presents, or causes to be presented, to an officer or employee of the department, a false or fraudulent claim for payment or approval.
>
> (b) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the department.
> …
>
> (d) Has possession, custody, or control of property or money used, or to be used, by the department and, intending to defraud the department or willfully to conceal the property, delivers, or causes to be delivered, less property than the amount for which the person receives a certificate or receipt.
>
> (e) Knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the department; or

344. Pursuant to the New Hampshire FCA, based on Defendant's material non-disclosures and other wrongful acts and omissions set forth above, Defendant is liable to the State of New Hampshire for treble damages, civil penalties, and all other relief authorized by law. N.H. Rev. Stat. Ann. § 167:61-b, et seq.

345. As a result of Defendant's violations, the State of New Hampshire has suffered damages in an amount to be determined at trial.

COUNT XX

New Jersey False Claims Act,
N.J. Stat. Ann. § 2A:32-C-1, *et seq.*

346. The allegations in the preceding paragraphs are incorporated by reference.

347. Relators also bring this action in the name of the State of New Jersey, against Defendant pursuant to the State of New Jersey False Claims Act ("FCA"), N.J. Stat. Ann. § 2A:32C-5.b.

348. Defendant, through their material non-disclosures and other wrongful acts and omissions set forth above, violated each of the following provisions of The New Jersey FCA, N.J. Stat. Ann. § 2A:32C-3, which create liability for any person who:

> "a. Knowingly presents or causes to be presented to an employee, officer or agent of the State, or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval;
>
> b. Knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State;
>
> …
>
> g. Knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State."

349. Pursuant to the New Jersey FCA, based on Defendant's material non-disclosures and other wrongful acts and omissions set forth above, Defendant is liable to the State of New Jersey for treble damages, civil penalties, and all other relief authorized by law. N.J. Stat. Ann. § 2A:32C-3.

350. As a result of Defendant's violations, the State of New Jersey has suffered damages in an amount to be determined at trial.

COUNT XXI

New Mexico Medicaid False Claims Act,
N.M. Stat. Ann. § 27-14-1, *et seq.*

351. The allegations in the preceding paragraphs are incorporated by reference.

352. Relators also bring this action on behalf of the State of New Mexico, against Defendant under the State of New Mexico Medicaid False Claims Act ("FCA"), N.M. Stat. Ann. § 27-14-7.B.

353. Defendant, through their material non-disclosures and other wrongful acts and omissions set forth above, violated each of the following provisions of the New Mexico FCA, N.M. Stat. Ann. § 27-14-4, which create liability for any person who:

> "A. presents, or causes to be presented, to the state a claim for payment under the Medicaid program knowing that such claim is false or fraudulent;
>
> B. presents, or causes to be presented, to the state a claim for payment under the Medicaid program knowing that the person receiving a Medicaid benefit or payment is not authorized or is not eligible for a benefit under the Medicaid program;
>
> C. makes, uses or causes to be made or used a record or statement to obtain a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false; [or]
>
> …
>
> E. makes, uses or causes to be made or used a record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the state, relative to the Medicaid program, knowing that such record or statement is false."

354. Pursuant to the New Mexico FCA, Defendant is liable to the State of New Mexico for statutorily defined damages sustained because of the acts of Defendant and such other relief as authorized. N.M. Stat. Ann. § 27-14-4.

355. As a result of Defendant's violations, the State of New Mexico has suffered damages in an amount to be determined at trial.

COUNT XXII

New York False Claims Act
N.Y. Fin. Law § 187 *et seq.*

356. The allegations in the preceding paragraphs are incorporated by reference.

357. Relators also bring this action on behalf of the State of New York, against Defendant under the State of New York False Claims Act, N.Y. Fin. Law § 187 et seq.

358. Defendant, through material non-disclosures and other wrongful acts and omissions set forth above, violated each of the following provisions of the New York False Claims Act, N.Y. Fin. Law § 189(1)(a), which creates liability for any person who: knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval.

359. Defendant, through material non-disclosures and other wrongful acts and omissions set forth above, violated each of the following provisions of the New York False Claims Act, N.Y. Fin. Law § 189(1)(b), which creates liability for any person who: knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.

360. Defendant, through material non-disclosures and other wrongful acts and omissions set forth above, violated each of the following provisions of the New York False Claims Act, N.Y. Fin. Law § 189(1)(c), which creates liability for any person who conspires to violate the New York False Claims Act.

361. Pursuant to the New York FCA, Defendant is liable to the State of New York for treble damages, civil penalties, and all other relief authorized by law. N.Y. Fin. Law § 189(1)(h).

362. As a result of Defendant's violations, the State of New York has suffered damages in an amount to be determined at trial.

COUNT XXIII

North Carolina False Claims Act,
N.C. Gen. Stat. § 1-605, *et seq*

.

363. The allegations in the preceding paragraphs are incorporated by reference.

364. Relators also bring this action on behalf of the State of North Carolina, against Defendant under the State of North Carolina False Claims Act ("FCA"), N.C. Gen. Stat. § 1-608(b).

365. Defendant, through their material non-disclosures and other wrongful acts and omissions set forth above, violated each of the following provisions of the North Carolina FCA, N.C. Gen. Stat. § 1-607(a), which creates liability for any person who:

> "(1) Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval.
>
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.
>
> …
>
> (7) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the State, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the State."

366. Pursuant to the North Carolina FCA, based on Defendant's material non-disclosures and other wrongful acts and omissions set forth above, Defendant is liable to the State of North Carolina for treble damages, civil penalties, and all other relief authorized by law. N.C. Gen. Stat. § 1-607(a).

367. As a result of Defendant's violations, the State of North Carolina has suffered damages in an amount to be determined at trial.

COUNT XXIV

Oklahoma Medicaid False Claims Act,
Okla. Stat. Tit. § 63-5053, et. seq.

368. The allegations in the preceding paragraphs are incorporated by reference.

369. Relators also bring this action in the name of the State of Oklahoma, against Defendant pursuant to the State of Oklahoma Medicaid False Claims Act ("FCA"), Okla. Stat. tit. § 63-5053.2(B).

370. Defendant, through their material non-disclosures and other wrongful acts and omissions set forth above, violated each of the following provisions of the Oklahoma FCA, Okla. Stat. tit. § 63-053.1(B), which create liability for any person who:

> "1. Knowingly presents, or causes to be presented, to an officer or employee of the State of Oklahoma, a false or fraudulent claim for payment or approval;
>
> 2. Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state;
>
> … or
>
> 7. Knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state."

371. Pursuant to the Oklahoma FCA, based on Defendant's material non-disclosures and other wrongful acts and omissions set forth above the State of Oklahoma has suffered damages in an amount to be determined at trial.

COUNT XXV

Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1, et seq.

372. The allegations in the preceding paragraphs are incorporated by reference.

373. Relators also bring this action in the name of the State of Rhode Island, against Defendant pursuant to the State of Rhode Island False Claims Act ("FCA"), R.I. Gen. Laws § 9-1.1-4(b).

374. Defendant, through their material non-disclosures and other wrongful acts and omissions set forth above, violated each of the following provisions of the Rhode Island FCA, R.I. Gen. Laws § 9-1.1-3(a), which create liability for any person who:

> "(1) Knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval;
>
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [or]
>
> …
>
> (7) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state…."

375. Pursuant to the Rhode Island FCA, based on Defendant's material non-disclosures and other wrongful acts and omissions set forth above, Defendant is liable to the State of Rhode Island for treble damages, civil penalties, and all other relief authorized by law. R.I. Gen. Laws § 9-1.1-3(a).

376. As a result of Defendant's violations, the State of Rhode Island has suffered damages in an amount to be determined at trial.

COUNT XXVI

Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181, et seq.

377. The allegations in the preceding paragraphs are incorporated by reference.

378. Relators also bring this action in the name of the State of Tennessee, against Defendant under the Tennessee Medicaid False Claims Act ("FCA"), Tenn. Code Ann. § 71-5-183(b)(1).

379. Defendant, through their material non-disclosures and other wrongful acts and omissions set forth above, violated each of the following provisions of the Tennessee FCA, Tenn. Code Ann. § 71-5-182(a)(l), which create liability for any person who:

> "(A) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval under the Medicaid program;
>
> (B) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim under the Medicaid program; [or]
>
> (C) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money, or property to the state, or knowingly conceals, or knowingly and improperly, avoids, or decreases an obligation to pay or transmit money or property to the state, relative to the Medicaid program."

380. Pursuant to the Tennessee FCA, based on Defendant's material non-disclosures and other wrongful acts and omissions set forth above, Defendant is liable to the State of Tennessee for treble damages, civil penalties, and all other relief authorized by law. Tenn. Code Ann. § 71-5-182(a).

381. As a result of Defendant's violations, the State of Tennessee has suffered damages in an amount to be determined at trial.

COUNT XXVII

Texas Medicaid Fraud Prevention Act
Tex. Hum. Res. Code § 36.001, et seq.

382. The allegations in the preceding paragraphs are incorporated by reference.

383. Relators also bring this action in the name of the State of Texas, against Defendant under the State of Texas Medicaid Fraud Prevention Act ("FCA"), Tex. Hum. Res. Code § 36.101(a).

384. Defendant, through their material non-disclosures and other wrongful acts and omissions set forth above, violated each of the following provisions of the Texas FCA, Tex. Hum. Res. Code § 36.002, which create liability for any person who, *inter alia*:

> "(1) knowingly makes or causes to be made a false statement or misrepresentation of a material fact to permit a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized;
>
> (2) knowingly conceals or fails to disclose information that permits a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized;
>
> …
>
> (12) knowingly makes, uses, or causes the making or use of a false record or statement material to an obligation to pay or transmit money or property to this state under the Medicaid program, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to this state under the Medicaid program; or

385. Pursuant to the Texas FCA, based on Defendant's material non-disclosures and other wrongful acts and omissions set forth above, Defendant is liable to the State of Texas for treble damages, civil penalties, and all other relief authorized by law. Tex. Hum. Res. Code § 36.052.

386. As a result of Defendant's violations, the State of Texas has suffered damages in an amount to be determined at trial.

COUNT XXVIII

Vermont False Claims Act,
Vt. Stat. Tit. 32, 630, et seq.

387. The allegations in the preceding paragraphs are incorporated by reference.

388. Relators also bring this action in the name of the State of Vermont, against Defendant under the State of Vermont False Claims Act ("FCA"), Vt. Stat. Ann. tit. 32, § 632(b).

389. Defendant, through their material non-disclosures and other wrongful acts and omissions set forth above, violated each of the following provisions of the Vermont FCA, Vt. Stat. Ann. tit. 32, § 631, which state that no person shall:

> "(1) knowingly present, or cause to be presented, a false or fraudulent claim for payment or approval;
>
> (2) knowingly make, use, or cause to be made or used, a false record or statement material to a false or fraudulent claim;
>
> …
>
> (8) knowingly make, use or cause to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the State; [or]
>
> (10) knowingly conceal or knowingly and improperly avoid or decrease an obligation to pay or transmit money or property to the State;

390. Pursuant to the Vermont FCA, based on Defendant's material non-disclosures and other wrongful acts and omissions set forth above, Defendant is liable to the State of Vermont for treble damages, civil penalties, and all other relief authorized by law. Vt. Stat. Ann. tit. 32, § 631(b).

391. As a result of Defendant's violations, the State of Vermont has suffered damages in an amount to be determined at trial.

COUNT XXIX

The Commonwealth of Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1, et seq.

392. The allegations in the preceding paragraphs are incorporated by reference.

393. Relators also bring this action on behalf of the Commonwealth of Virginia, against Defendant under the Commonwealth of Virginia Fraud Against Taxpayers Act ("FCA"), Va. Code Ann. § 8.01-216.5(A).

394. Defendant, through their material non-disclosures and other wrongful acts and omissions set forth above, violated each of the following provisions of the Virginia FCA, Va. Code Ann. § 8.01-216.3(A), which create liability for any person who:

> "1. Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> 2. Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> …
>
> 7. Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Commonwealth or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Commonwealth."

395. Pursuant to the Virginia FCA, based on Defendant's wrongful acts and omissions set forth above, Defendant is liable to the Commonwealth of Virginia for treble damages, civil penalties, and all other relief authorized by law. Va. Code Ann. § 8.01-216.3(A).

396. As a result of Defendant's violations, the Commonwealth of Virginia has suffered damages in an amount to be determined at trial.

COUNT XXX

Washington State Medicaid Fraud False Claims Act,
Wash. Rev. Code § 74.66.005, et seq.

397. The allegations in the preceding paragraphs are incorporated by reference.

398. Relators also bring this action on behalf of the State of Washington, against Defendant under the Washington State Medicaid Fraud False Claims Act ("FCA"), Wash. Rev. Code § 74.66.050(1).

399. Defendant, through their material non-disclosures and other wrongful acts and omissions set forth above, violated each of the following provisions of the Washington FCA, Wash. Rev. Code § 74.66.020(1), which create liability for any person who:

> "(a) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (b) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [or]
>
> …
>
> (g) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the government entity, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the government entity."

400. Pursuant to the Washington FCA, based on Defendant's material non-disclosures and other wrongful acts and omissions set forth above, Defendant are liable to the State of Washington for treble damages, civil penalties, and all other relief authorized by law. Wash. Rev. Code § 74.66.020(1).

401. As a result of Defendant's violations, the State of Washington has suffered damages in an amount to be determined at trial.

RELATORS DEMAND A TRIAL BY STRUCK JURY

Respectfully submitted,

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Attorneys for Relators

Certificate of Service

On this the 29th day of June, 2018, Plaintiff-Relator hereby certify that in compliance with Rule 4 of the Federal Rules of Civil Procedure, service of the Qui Tam Complaint has been executed as follows:

By Hand Delivery to:
United States Attorney for the Northern District of Alabama
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Birmingham, Alabama 35203

By Certified Mail to:
Attorney General of the United States of America
Department of Justice
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Washington, DC 20530-0001

By Certified Mail to:
The Attorney General's Office
California Department of Justice
Attn: False Claims Unit
455 Golden Gate Avenue, Suite 11000
San Francisco, CA 94102-7004

By Certified Mail to:
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Attorney General of the State of Colorado
ATTN: George A. Codding, Sr. Asst. Attorney General
Ralph L. Carr – Colorado Judicial Center
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Denver, CO 80203

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By Certified Mail to:
Hon. Pam Bondi
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